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Japan

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

This report is an overview of Japan's general legal and technical requirements for food and agricultural imports. While all sections of this report have been updated, the following sections have seen substantive revisions from the 2015 FAIRS report: Section II. Food Additives Regulations, Section V. Labeling Requirements, and Section VI. Other Specific Standards.

Note: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service at the U.S. Embassy/Tokyo for exporters of U.S. agricultural products. While great care was taken in the preparation of this report, the information provided may not be completely accurate due to either changes in policies since its preparation, or because clear and consistent information about these policies was not available at the time of publication. It is highly recommended that U.S. exporters verify the relevant import requirements with their foreign customers, who normally have the most updated information on local requirements and can research such matters with local authorities, prior to exportation. 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.

Contents

Section I. General Food Laws	3
Section II. Food Additives Regulations	3
Section III. Pesticides and Other Contaminants	6
Monitoring of Chemical Residues	7
Other Contaminants and Contributing Factors of Violation	8
Section IV. Packaging and Container Regulations	9
Section V. Labeling Requirements	9
Nutritional Labeling	11
Section VI. Other Specific Standards	12
Biotechnology Foods	12
Meat and Meat Products	13
Fruits and Vegetables and Unprocessed Grain Products	14
Frozen Fruits and Vegetables That Are Permitted Entry	14
Section IX. Import Procedures	15
Section X. Copyright and/or Trademark Laws	19
Appendix I. Government Regulatory Agency Contacts	20
Appendix II. Other Import Specialist Contacts	22

Section I. General Food Laws

There are four major laws in Japan pertaining to food safety and standards: the Food Safety Basic Law, Food Sanitation Law, Japan Agricultural Standards Law, and the Health Promotion Law. The Food Safety Basic Law sets the principles for developing a food safety regime and also establishes the role of the Food Safety Commission (FSC), a food-related risk assessment body. The Food Sanitation Law ensures the safety and sanitation of foods through the Ministry of Health, Labor and Welfare (MHLW), a food risk management agency. The law prohibits the sale of foods containing harmful substances. It also prescribes the standards for foods, additives, food containers and packages. The law is available in English on the Japan External Trade Organization (JETRO) website at:

<http://www.jetro.go.jp/en/reports/regulations/>.

The general requirements and standards are set by MHLW and apply to all types of foods, including imported foods. Imported foods that do not meet these requirements will not be allowed entry. These requirements and standards place the primary emphasis on ingredient and manufacturing standards. The Import Notification form should indicate if the product contains food additives such as preservatives, coloring, or flavorings. In addition, a certificate with a detailed description of the ingredients (names of the chemicals and international index numbers of the colors, etc.) and brief processing outline can be attached to each shipment in order to expedite import procedures. Details of food importing procedures may be viewed on the MHLW's website at:

<http://www.mhlw.go.jp/english/topics/importedfoods/1.html>.

Before shipping a new or unknown product to Japan, MHLW recommends that the Japanese importer deliver a small sample of the product to be imported to the Japanese customs and MHLW port inspectors' office with a certificate guaranteeing compliance with required product regulations (for more information on commercial samples, see Section IX Import Procedures). These samples should be inspected to ensure that no importation problems exist before the actual product is commercially exported to Japan. It is strongly recommended that products not be shipped until product compliance has been verified. If a port official questions whether the product conforms to the food safety standards (e.g., possible inappropriate use of additives, contamination by toxic materials, a history of violations, etc.), s/he can request the importer perform a "voluntary" test at a registered Japanese laboratory. However, if the exporter/importer tests the product at an MHLW-registered laboratory in the United States prior to shipment and attaches the test results to confirm the product specification, the test at the port can be waived. For more information, see "U.S. Laboratories Certified by the Government of Japan" in Section VIII below..

The Ministry of Agriculture, Forestry and Fisheries (MAFF) is also involved in food safety risk management, mainly through the Japan Agricultural Standards (JAS) Law, and is involved in animal and plant health protection through a series of quarantine laws. A summary of animal and plant quarantine regulations related to JAS standards can be found on page 98 of the "Handbook for Agricultural and Fishery Products Import regulations 2009," which can also be viewed on JETRO's website at: https://www.jetro.go.jp/en/reports/regulations/pdf/agri2009e_1007p.pdf.

Section II. Food Additives Regulations

Only additives that have been reviewed by the FSC and approved by MHLW may be used in foods and beverages sold in Japan, and imports of product found to contain residues from unapproved additives will not be allowed for sale. Please note that food additive regulations also apply to compounds used as processing aids or antimicrobial treatments. According to Japanese food safety legislation, any “substances used in or on food in the process of manufacturing food, or substances used for the purpose of processing or preserving food” are considered and treated as a food additive, irrespective of whether the compound leaves a detectable residue.

There are four categories of additives: Designated Additives, Existing Additives, Natural Flavoring Agents, and Ordinary Foods Used as Food Additives. Definitions for each of the above food additive categories can be found at MHLW’s “Food Additive” website at:

<http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html>. It is important to note that an approved substance in the “Designated Additives” category may be limited to use on a specific product at a set level and only permitted for specific use. For a full list of substances approved as Designated Additives, as well as their approved uses and tolerances, please refer to MHLW’s “Food Additive” website and the Japan Food Chemical Research Foundation (FFCR) [Standards for Use of Food Additives](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/e-foodadditives) website at: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/e-foodadditives>.

Among the four categories of food additives in the Japanese food additive regulations, the additives that often cause the most issues for regulatory noncompliance among U.S. products being exported to Japan are “designated food additives”. This issue of noncompliance with Japanese regulations can occur for various reasons, including different level/concentration of use, limitation of scope of use (i.e., the substance is allowed for all kinds of foods in the United States, but only for a limited scope of food in Japan), and/or specification of the food additive. Please see the “Standards for Use 2016 October 27” and refer to the columns entitled “Target Foods,” “Maximum Limits,” and “Limitation for Use.” at: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/standr.use>

Though there are no substantial changes in the regulation and its practice, the labeling of food additives, including post-harvest fungicides, is handled by the Consumer Affairs Agency (CAA). For details, please refer to the FFCR’s Standards for Labeling website at: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa-labeling>.

To facilitate customs clearance, the following information should be provided 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.
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 reviews applications for the approval of new food additives and the approval of new uses (e.g., use of additives for new target foods) and tolerances for additives that have been approved

previously. Though MHLW is the contact point for the application, after a completeness check, the application is sent to the FSC for a risk assessment of the substance. After completion of the risk assessment, the FSC reports the result to MHLW. MHLW, as a risk management body, decides the specific application level for each food on the approval of food additives, in part, based on the concept of the acceptable daily intake (ADI) of the substance which the FSC may propose to set, depending on the known toxicity of the substance. There are cases where the FSC does not establish an ADI when the toxicity of the substance is indicated. Thus, MHLW looks at all of the products in which a certain additive is used prior to granting approval. For example, a preservative approved at a certain level for margarine may not be approved as a preservative for mayonnaise, depending on the scope of the food category which the application covers, in case the estimated dietary exposure from existing applications is close to, or exceeds, its ADI. In the above example, for the additive to be approved for use in mayonnaise, an applicant would have to supply MHLW with the relevant technical data to demonstrate that the additional use would not exceed the ADI. The application procedure for approval of new food additives or new uses of approved additives is described in detail in the “Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives,” which can be obtained online at: <http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/dl/tenkabutu-shiteikijunkaiseishishin-english.pdf> .

In June 2014, MHLW established the Food Additive Designation Consultation Center (FADCC) to assist companies with applications for food additive use in Japan. MHLW considers that the FADCC, located in the National Institute of Health Sciences and staffed by former food additive regulatory specialists, will help companies in preparing more complete applications, thereby reducing the time to obtain regulatory approval. The FADCC provides consultations free of charge; however all interaction must be face-to-face. Additionally, as all interactions are only in Japanese, the FADCC requests that non-Japanese applicants be accompanied by an interpreter, if necessary. More information on the FADCC can be found online at: http://www.nihs.go.jp/dfa/fadcc_ehome.html.

Additives in Alcohol

Additives used in alcoholic beverages require additional approval by the National Tax Agency (NTA) under the Liquor Tax Act. Per Japan’s Food Sanitation Law, MHLW approval is required before the application to the NTA can begin. NTA requirements for applications are as follows:

1. Name of the material to be specified
2. Item of liquor that the additive will be blended with
3. Purpose of use
4. Usage guidelines
5. Efficacy and component analysis
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
9. Sales agency’s name and address

According to sources, approval for additives used in alcoholic beverages can be obtained within five to six months after the formal acceptance of the application by the NTA (if the use of the additive is deemed appropriate).

For more information, please consult the following website (as of December 13, 2015, available only in Japanese at: <https://www.nta.go.jp/shiraberu/senmonjoho/sake/gijutsu/mokuji.htm>).

Section III. Pesticides and Other Contaminants

On May 29, 2006, Japan implemented new regulations governing agricultural chemical residues, feed additives and veterinary drugs (hereinafter referred to as agricultural chemicals) in food. Prior to implementation of these regulations, MHLW announced provisional maximum residue levels (MRLs) for 758 agricultural chemicals, in addition to around 10,000 existing official MRLs. These MRLs remain “provisional” until they are reviewed, and while many have already finished the process, reviews of other MRLs will continue until completion of the project. Since 2006, MHLW has requested the FSC perform risk assessments for a total of 599 out of 758 substances, 315 of which had been completed as of December 2015. Together, the existing MRLs and the provisional MRLs make up the “positive list.” Foods found to contain residues exceeding the MRL levels on the positive list are regarded as violations of the Food Sanitation Law and are rejected at the port. A single violation can lead to “enhanced monitoring” (generally 30 percent) for all imports of the same product from that country. After reaching 60 clean tests (among the entire industry, excluding the violator), MHLW will lift the 30 percent enhanced monitoring policy. At the same time, the violator (exporter) in question will face a “100 percent hold and test” policy, in which each shipment of the same commodity from the exporter has to be tested by Japan to show the residue level is below the Japanese acceptable MRL before clearing customs. After reaching 60 clean tests from the exporter’s shipments, MHLW will lift the 100 percent hold and test policy. Alternatively, if no further detection occurs for one year following the initial violation, the 30 percent enhanced industry-wide monitoring requirement can be lifted. Additionally, the increased monitoring policy on the violating exporter can be lifted after one year of no further detections, even if the requirement of 60 clean tests has not yet been reached. For more details, please consult “I. Implementation Guidelines for Monitoring Inspections Concerning Imported Foods, 2. Targets, (3) Number of specimens” in MHLW’s “Implementation of ‘Imported Foods Monitoring Plan for FY 2016” (<http://www.mhlw.go.jp/english/topics/importedfoods/16/notice-2016-0331-01.html>).

After two violations of a specific MRL by two different operators, all imports of the same product from that country could be subject to a costly Inspection Order of 100 percent hold and test measures, which could involve lengthy delays at the port. Following multiple violations by different operators, MHLW requires 300 clean test records and two years with no further violations before removing an Inspection Order (industry-wide 100 percent hold and test).

For combinations of chemicals and commodities that have no official or provisional MRLs, MHLW has established a uniform tolerance of 0.01 ppm as the maximum allowable limit for most chemicals. Please note that MHLW has also listed 19 agrochemicals and other chemical substances known as "Not detected" that are banned from use in foods (<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p-ND>). In addition, there are 65 exempted

substances that have been determined not to pose adverse health effects (<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p-ES>).

MHLW has established its own crop categorization that is employed in the designation of MRLs, which may not match exactly with U.S. crop categorizations (see MHLW Food Classifications, <http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/dl/r04.pdf>). For a comparison of U.S. and Japanese MRLs, see: <https://www.globalmrl.com/>.

MAFF and MHLW are currently in the process of re-organizing the GOJ's crop classifications to be in line with CODEX Classification of Foods and Animal Feeds (<ftp://ftp.fao.org/codex/meetings/ccpr/ccpr38/pr38CxCl.pdf>). Currently, the draft for the new crop classifications is available to the public on MAFF's website (http://www.maff.go.jp/j/nouyaku/n_sassin/group/sakumotu_bunrui.html). Please note that the draft classification is found in Japanese and English at the bottom of website, although the site is primarily written in Japanese. As CODEX is still in the process of establishing crop classifications for all commodities, Japan's re-organization of crop classifications is expected to take some time to complete.

For residues in processed foods that do not have specific MRLs, MHLW will test the product based on the relative proportion of ingredients to that of the final product.

Other information in English about the positive list system, including the actual MRLs, can be found on MHLW's [Positive List System](http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html) webpage (<http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html>).

Monitoring of Chemical Residues

Monitoring for chemical residues is conducted by MHLW quarantine offices (for imported crops) and local government laboratories (for both imported and domestically produced crops, collected mostly from retail shelves). The purpose of the monitoring test is to check whether crops and livestock products in the marketplace comply with established MRLs and other food safety regulations. Any product found to contain a substance in violation of the MRL regulations will not be allowed to be sold in Japan.

Since 1985, MHLW has conducted surveys of residues, including pesticides and veterinary drugs without MRLs, to obtain basic data for the establishment of MRLs. Monitoring test results typically show that less than 0.1 percent of the samples tested were above the established MRLs. Crops not meeting the standards and specifications of the Food Sanitation Law, including MRLs, must be discarded, re-exported, or re-directed to non-food use. Each year MHLW decides on a specific monitoring plan. Details of the FY2016 monitoring plan can be found at the following website: http://www.mhlw.go.jp/topics/yunyu/keikaku/dl/16_en.pdf.

Please note that enhanced inspection plans after a violation will be issued separately.

The report of FY2015 inspection results can be found at the following website: <http://www.mhlw.go.jp/english/topics/importedfoods/15/dl/15-08a.pdf>.

Establishment of MRLs for Agrochemicals

To establish an MRL, concerned parties must submit an application to MHLW, which will go through 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). Details of the application procedure for establishment and revision of MRLs used outside Japan are available at the following MHLW website at: <http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html>.

Please note that the executive summary of the application should be in Japanese, though other accompanying documents, such as study reports, may be written in English. MHLW does not require translation of the original reference articles.

On May 14, 2013, MHLW announced that it would begin accepting applications for Import Tolerances (IT) even if the MRL for the agrochemical has not yet been finalized in the exporting country. Before this announcement, the applicant was allowed to make the IT application only after the official establishment of the MRL in the home country. MHLW's new system will allow import tolerance applications to start the review process 12 to 15 months earlier than in the previous system, potentially minimizing delays in the establishment of new MRLs. The new system will also serve as an incentive for the chemical developers to minimize any MRL differences between the United States and Japan. For more details, please refer to GAIN Report [JA3023](#).

Other Contaminants and Contributing Factors of 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. Please note that the list includes some items that MHLW no longer requires testing for; However, MHLW may test for these again at any time, as they are still under the inspection order.

1. Aflatoxin levels in peanuts, peanut products (including peanut butter), pistachios, processed products containing pistachios (30 percent or more), nuts, spices, and some grain products;
2. Enterohemorrhagic E. coli O26, O103, O111 and O157 (beef, horse meat, and Unheated meat products to be consumed without further cooking, such as natural cheese);
3. Norovirus (bivalves and other shellfish to be eaten raw);
4. Hepatitis A Virus (bivalves and other shellfish to be eaten raw);
5. Mercury (fish and shellfish);
6. PCB (beef, pork, fish and shellfish);
7. Poisonous fish;
8. Shellfish poisons (diarrhea poison and paralytic poison of bivalves);
9. Cyanogen (butter beans, white beans, saltani beans, etc.);
10. Methanol in distilled liquors and wines;
11. Gossypol in cottonseeds other than for oil extraction;

12. Salmonella in meat meant to be consumed raw;
13. Listeria (unheated meat products to be consumed without further cooking and natural cheese);
14. Trichina in game birds, etc;
15. Radioactive substances, usually in foods of European origin;
16. Decomposed or deteriorated foods of all kinds.

Irradiation

Though irradiation is used as a tool to eliminate foodborne pathogens and prevent food poisoning in many countries, it is not allowed in Japan, except in the case of potatoes, which may be irradiated but also must be labeled as such. Food items for inspection include meat, dairy, seafood, other agricultural produce and their processed products.

For further details, please refer to the “Implementation of ‘Imported Foods Monitoring Plan for FY 2016’” (<http://www.mhlw.go.jp/english/topics/importedfoods/16/notice-2016-0331-01.html>).

Section IV. Packaging and Container Regulations

In accordance with Article 16 of the MHLW Food Sanitation Law, no person shall sell, manufacture, or import with the intent to sell or use in business any apparatus, container, or package which contains or bears toxic or injurious substances and may injure human health, or any apparatus, container, or package which may injure human health by having harmful influence on foods and additives through contact therewith.

MHLW has established specifications for synthetic resins, metal cans, and containers/packages made of glass, ceramic, enamel, or rubber. For further details, please refer to the following websites:

- JETRO: <http://www.jetro.go.jp/en/reports/regulations/>
 1. See “Chapter I - Food, Additives, Apparatus and Containers and Packaging”, under the “Ordinance for Enforcement of the Food Sanitation Act”;
 2. and “Chapter III - Apparatus and Containers and Packaging” under the “Food Sanitation Act”.
- Japan Food Chemical Research Foundation (FFCR):
<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/appar-pac>.

Private industry is required to pay all costs associated with recycling. For imported products, part of the recycling cost is borne by importers. Importers are responsible for making sure that there are appropriate recycling labels on all packaging and containers used for imported goods. However, some Japanese importers may ask their suppliers overseas to cooperate in supplying appropriate recycling labeling. More details can be found on the Ministry of Economy, Trade and Industry’s website (<http://www.meti.go.jp/english/information/data/cReEffect01e.html>) and in GAIN report [JA3022](#).

Section V. Labeling Requirements

Labeling Required by Japanese laws

The Japanese Diet established a new, comprehensive Food Labeling Law on June 28, 2013. The law mandates nutritional labeling and inclusion of allergen information on all pre-packaged processed food products, including imports. The law took effect in April 2015 and nutritional labeling requirements have a five-year transition period until March 31, 2020. For further details, please refer to [JA4043](#).

The Food Labeling Law requires that the label on retail packages for imported food products include the following information, in Japanese:

- Name of the product;
- Country of origin;
- 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;
- Storage instructions;
- Labeling of certain biotechnology ingredients where the genetically modified content of the labeled ingredient exceeds 5 percent.

Since September 2009, GE food labeling has been handled by the CAA. However, the regulation and its implementation have not changed substantially. For more information on GE labeling, please refer to the websites below:

MHLW: <http://www.mhlw.go.jp/english/topics/foodsafety/dna/index.html>

CAA: <http://www.caa.go.jp/en/pdf/syokuhin736.pdf>

- Organic labeling, including mandatory third party certification for products labeled as “organic.” For more information, please click the link below:
<http://www.maff.go.jp/e/policies/standard/jas/specific/organic.html>
- Note there were 56 processed foods, which had additional Individual Quality Labeling Standards. The Food Labeling Standard, which became effective in April 2015, consolidated these individual standards into one labeling standard. There is no English translation available, but details of the Quality Labeling Standards can be found on the following CAA website at: http://www.caa.go.jp/foods/pdf/150320_kijyun.pdf.

- Allergen labeling is required by the CAA on foods containing any of the seven ingredients known to cause significant allergic reactions: wheat, buckwheat, egg, milk, peanuts, prawn and crab. The CAA also recommends that any of the 20 additional allergens be listed on the label when present in the food: abalone, mackerel, squid, salmon, salmon roe, sesame, walnuts, cashew nuts, soybean, Matsutake mushrooms, orange, kiwi fruit, peach, yam, apple, banana, beef, chicken, pork and gelatin. For details, please see the CAA website at: <http://www.caa.go.jp/foods/pdf/syokuhin13.pdf>.

The minimum font size required for labels is 8-point for all characters. It is recommended that the importer double-check the labels to ensure conformity.

Nutritional Labeling

While nutritional labeling is currently voluntary in Japan, it will be mandatory by March 31, 2020, under the proposed new Food Labeling Standard. For more information on the future nutritional labeling regime, please refer to [JA4043](#).

Through the new Food Labeling Standard's five-year grace period for nutritional labeling requirements, the CAA will continue to require that food manufacturers provide certain nutritional information on food labels when a nutrient declaration is made; the U.S. nutritional fact panel is not acceptable. When a nutrient content claim or nutrient function (see descriptions below) claim is made, then five basic nutritional components must be labeled:

- 1) calories (kilocalories);
- 2) protein (grams);
- 3) fat (grams);
- 4) sugar or carbohydrate (grams);
- 5) salt equivalent (grams) (sodium (milligrams) x 2.54 / 1000).

In addition to the five required nutritional components, companies are also able to voluntarily label other nutritional components such as vitamins and minerals. The content of each component per unit of food must be provided (e.g., 100 g, 100 ml, 1 serving, 1 package, etc.). The label must use a font size of at least 8-point, unless total labeling area is less than 30 cm².

For details, please consult the CAA website at: <http://www.caa.go.jp/en/pdf/syokuhin569.pdf> .

For protein, dietary fiber, zinc, potassium, calcium, iron, copper, magnesium, niacin, pantothenic acid, biotin, Vitamin A, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D, Vitamin E, Vitamin K and folic acid, nutrient function or nutrient content claims such as "rich in", "containing" or "enhanced" must meet minimum content level standards required by the [Food Labeling Standards](#) (table 12 on page 516). Claims that include the terms "no", "less" or "reduced" in regards to calories, fat, saturated fatty acid, cholesterol, sugar or sodium, must also meet maximum content standards required by the [Food Labeling Standards](#) (table 13 on page 523). For example, when a "no sodium" or "low or less sodium" claim is made, the sodium content must be lower than 5 mg and must not be greater than 120 mg per 100 g of food respectively, and when a "no fat" or "low or less fat" claim is made, the fat content must be lower than 0.5 g and must not be greater than 3 g per 100 g of food, respectively.

Japan has strict rules on functional and nutritional claims on food labeling. Food for Specified Health Uses (FOSHU) refers to foods containing ingredients with functions for health and officially approved to claim its physiological effects on the human body. FOSHU is intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol. In order to sell a food as FOSHU, the assessment for the safety of the food and effectiveness of the functions for health is required, and the claim must be approved by the CAA and cleared by MHLW. More information can be found at: <http://www.caa.go.jp/en/pdf/syokuhin569.pdf> and <http://www.caa.go.jp/en/pdf/syokuhin338.pdf>.

In addition to FOSHU, the CAA added a new category of “function claim” food in April 2015. This new category of voluntary labeling is known as Food with Functional Claims (FFC) and allows companies to display a product’s specific health benefit and an associated area of the human body on retail food packaging. FFC will include not only processed products, but also fresh food. The FFC registration process is more affordable and faster than the registration process for Food for FOSHU. More information can be found in [JA5025](#).

Section VI. Other Specific Standards

Biotechnology Foods

The Government of Japan (GOJ) requires both an environmental and food safety assessment of “genetically engineered (GE) products” before they can be exported to Japan.

No food or beverages or their ingredients may contain “materials” produced through recombinant DNA techniques that have not been approved by the GOJ. As of December 12, 2016, Japan has approved 309 GE events, counting stacks as different events, for food use. The latest list can be found at the following MHLW website: <http://www.mhlw.go.jp/english/topics/food/pdf/sec01-2.pdf>. MHLW coordinates Japan’s food safety assessment for GE plants. Upon receipt of an application that has been prepared in accordance with guideline requirements, MHLW will ask the FSC’s expert committee to begin a risk assessment to determine biological characteristics and the potential impact on public health. MHLW and the FSC maintain a science-based approval process, and varieties of genetically modified plants that have been approved include soybeans, canola, corn, potatoes, sugar beets, cotton 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 GOJ. Any shipment found to contain an unapproved variety may not be imported into Japan.

It is important to note that the non-protein food additives produced by genetically modified organisms also have to be “checked” by MHLW and the FSC. Although the products as such (e.g., amino acids) are highly purified and contain no DNA fragment, the technical providers need to consult with MHLW on the level of purification and substantial equivalence with the products produced by conventional methods.

As the Japanese environmental safety review is based on the Cartagena Biosafety protocol, an environmental safety review – conducted by MAFF – is required only for living modified organisms (LMOs). Therefore, theoretically, the ingredients contained in processed products are not required to

have environmental approval. Bioindustry Innovation Organization (<https://www.bio.org/articles/product-launch-stewardship-food-and-agriculture-section>) and CropLife (<https://croplife.org/plant-biotechnology/stewardship-2/product-launch-stewardship/>) release product launch stewardship policy for their members to minimize regulatory discrepancies in approval timing with trading partners. MAFF also performs feed safety assessments (where appropriate) for biotechnology products.

For more information on Japan's regulatory approach to biotechnology, please refer to the MHLW website <http://www.mhlw.go.jp/english/topics/food/index.html>, <http://www.mhlw.go.jp/english/topics/foodsafety/dna/index.html>, and GAIN report [JA6050](#).

Organic Foods

MAFF is also responsible for organic food standards through the JAS Law. The JAS Law, regulations pertaining to organic food, and other quality-based food labeling regulations are located on the following MAFF website at: <http://www.maff.go.jp/e/policies/standard/jas/index.html>

On January 1, 2014, the United States and Japan entered into an equivalency arrangement for organic plant products (including fungi and plant-based processed products). For details, please refer to the USDA/Agricultural Marketing Service (AMS)/National Organics Program (NOP) website at: <https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program>.

Meat and Meat Products

Fresh, prepared, or preserved meat and meat products going into Japan from the United States must be accompanied by USDA/FSIS Form 9290-1 "Certificate to Export to Japan" and FSIS Form 9060-5 (formerly MP Form 130) "Meat and Poultry Export Certificate of Wholesomeness." These certificates are issued at the slaughtering or processing facility by a qualified USDA meat and poultry inspector. Export requirements are described on the FSIS Export Library webpage at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/Japan>.

Production of beef and beef products exported to Japan must adhere to the requirements of the Less than 30 month (LT30) Age-Verification Quality System Assessment (QSA) Program for Japan, due to BSE findings in the United States in 2003. Under this program, all beef sent to Japan must be from cattle less than 30 months of age at the time of slaughter and produced in facilities audited and approved by AMS. The official listing of eligible suppliers in the LT30 QSA Program for Japan and a description of the specific requirements can be found on the AMS website at: <https://www.ams.usda.gov/services/imports-exports/lt30-qa>.

Japanese importers are responsible for appropriately labeling meat and meat products in the Japanese market. Labels that comply with Japanese food labeling regulations are not required for imported meat and meat products to successfully clear through customs and quarantine inspections. However, a Japanese importer may ask a U.S. producer for detailed product information (including ingredients and processing diagrams) in order to develop an appropriate Japanese language label and/or to ensure that MAFF and MHLW quarantine officials have sufficient information to evaluate the product for Japanese

regulatory compliance. The development and approval of labels compliant with Japanese food labeling regulations are the sole responsibility of Japanese importers. Application of Japanese language labels in the United States may be requested by Japanese customers, but is not required by the Government of Japan.

Fruits and Vegetables and Unprocessed Grain Products

A USDA Phytosanitary Certificate PPQ Form 577 must accompany fresh, uncooked, or partially dehydrated fruits and vegetables and unprocessed grain products. Certain fresh fruits and vegetables are currently prohibited under Japan's quarantine law, including apricots, bell peppers, chilies, eggplant, peaches, pears, radishes, sweet potatoes and yams. For more information, contact your local Animal and Plant Health Inspection Service (APHIS) office or consult the USDA-APHIS website at: <https://www.aphis.usda.gov/wps/portal/aphis/home/>.

Frozen Fruits and Vegetables That Are Permitted Entry

Those frozen fruits and vegetables which are permitted entry by the Japanese government in their fresh form (not heated prior to freezing) may be certified by the U.S. processor, exporter, state department of agriculture, or AMS (<https://www.ams.usda.gov/>) Certification requires that the following information be placed on the shipper's invoice, which will accompany the product:

1. Date of product freezing
2. Temperature of freezing (must be at least zero degrees Fahrenheit)
3. Name and signature of responsible company official or representative
4. Title of company
5. Date of signature
6. Name of company
7. Product description
8. Quantity of product being shipped

It is possible that, if certain conditions are met upon arrival of the initial shipment of a frozen product, the GOJ may waive the document and/or inspection requirements for all subsequent shipments. For more information, contact USDA/Tokyo at agtokyo@fas.usda.gov.

Section VII. Facility and Product Registration

Specific to the LT30 QSA Program, all establishments producing beef and beef products for export to Japan must be listed on the AMS Official Listing of Approved Suppliers for the USDA QSA Program for Japan (see <https://www.ams.usda.gov/?dDocName=STELPRDC5070251>).

There are no other specific facility registration requirements for export to Japan.

As described in the Import Procedures section below, quarantine and customs officials evaluate import notifications for individual shipments; there is no product registration requirement. However, MHLW administers several voluntary product registration processes that serve to expedite the import quarantine process. These programs are listed on the MHLW website (in English) at:

<http://www.mhlw.go.jp/english/topics/importedfoods/1-5.html>. (Please note that these processes are customarily initiated by Japanese importers rather than U.S. exporters.)

Section VIII: Other Certification and Testing Requirements

There are several levels of testing which can be “required” by the GOJ to allow importation into Japan.

Although, pre-export testing may not be required, it can be helpful in the case of a new or unknown product that will be exported to Japan. MHLW recommends that the Japanese importer deliver a small sample of the product to the Japanese customs and MHLW port inspectors’ offices with a certificate guaranteeing compliance with required product regulations. During the review process, the Japanese official may request the importer to test the sample at a MHLW- registered domestic laboratory. However, if the exporter/importer tests the product at an MHLW-registered laboratory in the United States prior to shipment and attaches the test results to confirm the product specification, the test at the port can be waived. For more information, see “U.S. Laboratories Certified by the Government of Japan” in Section VIII below.

Finally, prefectural-level health authorities (with over 7,000 inspectors) also perform random tests on samples from domestic and imported products located in local retailers. For more information on the relationship between national and local government testing systems, please refer to MHLW’s home page at: <http://www.mhlw.go.jp/english/topics/foodsafety/administration/dl/01.pdf>.

For information regarding what certificates are required for import, please refer to the December 2015 FAIRS Certification report.

Sometimes, there is confusion between the “test requirement by Japanese Government (or Japanese port officials)” and a test that a trading partner would like to have to make sure the product meets Japanese food safety standards. It is worthwhile for exporters to understand the difference between the mandatory requirements in Japanese regulations versus a business decision by importers seeking to lower their risk.

U.S. Laboratories Certified by the Government of Japan

MHLW has certified certain U.S. laboratories as eligible to test foods and beverages for compliance with Japan’s Food Sanitation law for export to Japan. If an analytical certificate from a laboratory approved by MHLW accompanies the shipment, and the certificate is complete and satisfactory, no additional tests for the products will be required by MHLW when the product is inspected at the port of entry into Japan. A full list of MHLW-approved U.S. laboratories is available on the following MHLW website: <http://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf>.

Section IX. Import Procedures

Firms interested in importing food, food additives, containers/packages, or any other food related apparatus into Japan must submit a “Notification Form of Food Importation” to the Food Sanitation Inspection Section of the MHLW Quarantine Station. The Quarantine Station will examine the product to determine if it conforms to the Japanese Food Sanitation Law. Products that require examination will be inspected on the spot at a designated bonded warehouse. Samples will be taken and forwarded for

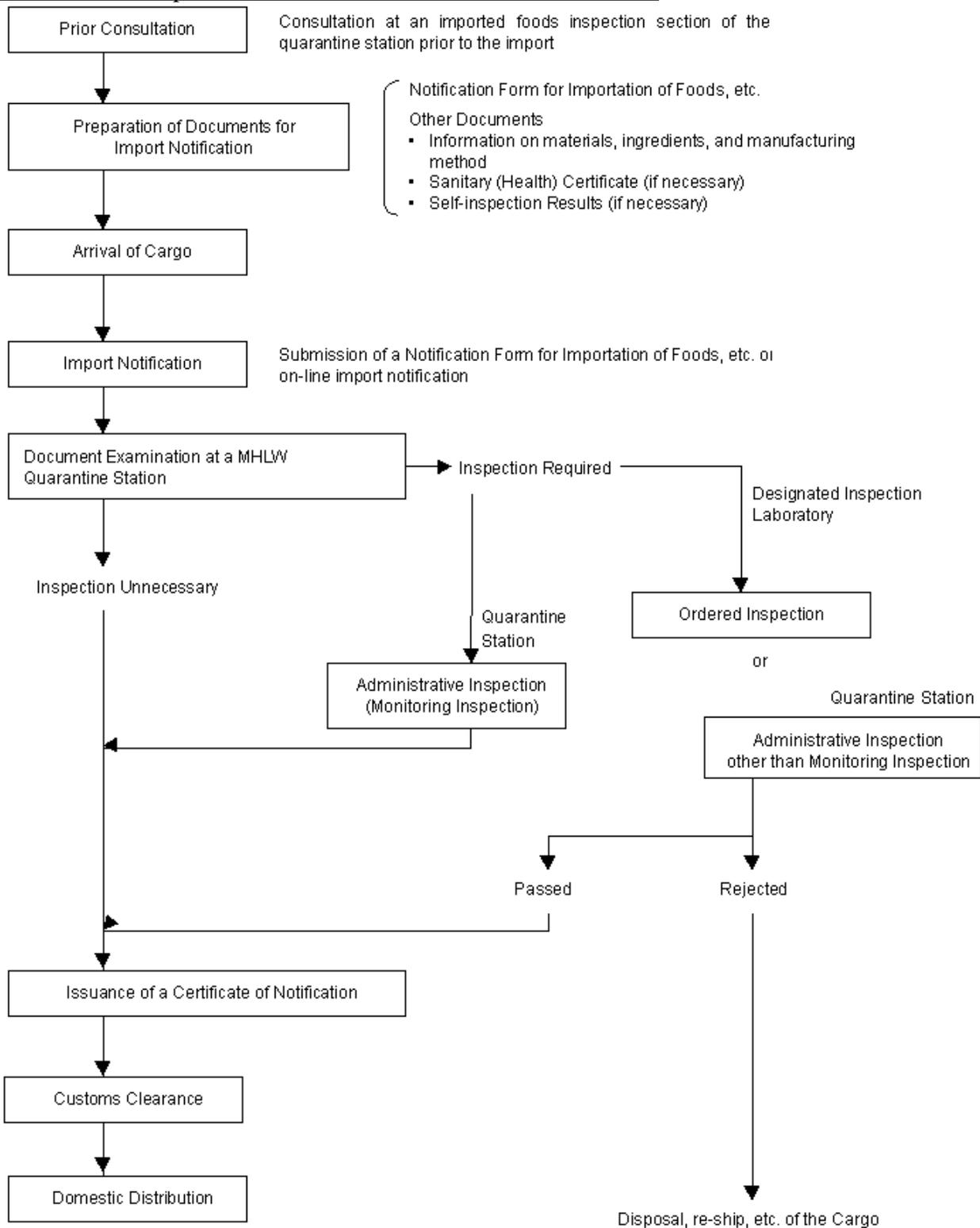
laboratory analysis. The product will be allowed entry into Japan once it is examined and found to be in compliance with Japanese food regulations. The Notification Form is stamped if the food requires no examination and is found to be in compliance with the Japanese Food Sanitation Law. Please refer to the flowchart below.

Details on food importing procedures may be viewed at:

<http://www.mhlw.go.jp/english/topics/importedfoods/1.html> . Though some aspects appear dated, JETRO's valuable and detailed Q&A on imported foods is available at:

https://www.jetro.go.jp/costarica/mercadeo/handbook_importedfoods.pdf.

Procedures of Import Notification of Foods and Related Products



When products are imported as commercial samples or for “internal company consideration,” and it is clear that the products will be used to decide whether or not to import the product in the

future, then the Notification Form is not required. However, depending upon the product and/or the Quarantine Station, Customs officials may require a memorandum or other document attesting that the product is a sample only to be used for “internal company consideration.” While there are no set restrictions on the volume of products permitted entry as commercial samples, the volume should not exceed what a Quarantine Station official would consider a reasonable or justifiable amount.

When products are being imported only to be exhibited at a trade fair and will be neither sold nor contracted for, then the Notification Form is not required. However, if the product is to be distributed to an unspecified number of 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, Customs officials may require a memorandum or other document attesting that the product is only to be used “for exhibition at a trade fair.” While there are no set restrictions on the volume of products permitted entry for tradeshow exhibition purposes, the volume should not exceed what a Quarantine Station official would consider a reasonable or justifiable amount.

With any attempt to avoid the standard import notification process, it is good practice to conduct extensive consultations in advance with the importing party and the relevant Quarantine Station to minimize the possibility of delays or disruptions at the border.

Required Importation Documents

Import documents required for entry into Japan are as follows:

1. Import Notification - Two copies
2. Health Certificate
3. Results of Examination
4. Documents showing the ingredients, additives and the manufacturing process (Manufacturer Certification)

Cargo found in violation of the Food Sanitation Law must be re-exported, destroyed, or otherwise discarded.

In addition, processed foods that are imported for the first time must contain additional documents with more detailed information than that stated on the import notification, including information about raw materials, ingredients, and manufacturing processes. Importing companies should be able to guide exporters through the required steps and appropriate level of detail needed for these documents.

Bovine free certification

For processed foods that could possibly contain ingredients from ruminants, such as gelatin and collagen, importers must certify through U.S. suppliers that the ingredients are not derived from ruminants in the United States due to BSE concerns. Dairy products are exempted from this requirement. Details are found in GAIN report [JA4017](#).

24 Hour Advance Notice System

On March 1, 2014, Japan Customs began implementing a 24 hour advance notice system, similar to existing systems in the United States and several other countries, to improve security and prevent terrorism. Details are found in GAIN report [JA8502](#).

Section X. Copyright and/or Trademark Laws

The international registration of trademarks under the Madrid Protocol is available in Japan. For more information on Japan's trademark registration, please refer to the Japan Patent Office website at: <http://www.jpo.go.jp/english/faqs/madrid.html>.

Appendix I. Government Regulatory Agency Contacts

The following are names and address of offices you can contact to receive detailed information on regulations and requirements to import into Japan.

Import Duties

The Tokyo Customs Office (TCO) will provide advance ruling on your product's import duties. An official ruling on the tariff category to determine the tariff rate and applicability of import quotas can be obtained by Japanese importers by providing product samples to:

Customs Counselor's Office
(ZEIKAN SODANKAN SHITSU)
Tokyo, Customs Office
2-7-11, Aomi, Koto-ku, Tokyo 135-8615
Tel: 81-3-3529-0700

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

Health Standards

Establishment of Health Standards is administered by:
Standards and Evaluation Division
Department of Human Health and Environment
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labor, and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo
Tel: 81-3-3595-2341
Tel: 81-3-3501-4868

Practice and enforcement of Health Standards are administered by:
Office of Import Food Safety
Department of Human Health and Environment
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labor, and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo

Animal Health / Quarantine

List of MAFF Animal Quarantine Service Contact Information (Airports / Seaports)

at:<http://www.maff.go.jp/aqs/english/contactus.html>

Labeling Regulations

Consumer Affairs Agency

Government of Japan

Sanno Park Tower, 2-11-1 Nagata, Chiyoda, Tokyo, 100-6178

Tel: 81-3-3507-8800

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

Additional Assistance can be obtained by contacting:

Office of Agricultural Affairs

U.S. Embassy

UNIT 9800, Box 480

DPO AP 96303-0480

Tel: 81-3-3224-5102

Fax: 81-3-3589-0793

Appendix II. Other Import Specialist Contacts

World Trade Organization (WTO) Enquiry Points

Each member government is responsible for the notification procedures associated with agreements under the WTO. Issues in this report relate to the Sanitary, Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. WTO obligations include notifying to the WTO any significant trade-related proposals that are not substantially the same as international standards, providing copies of the proposed regulation upon request, allowing time for comments, and also providing upon request copies of other relevant documents on existing regulations related to food and agriculture. Information on Japan's regulations, standards and certification procedures can also be obtained through the Inquiry Point listed below:

Standards Information Service
International Trade Division
Economic Affairs Bureau
Ministry of Foreign Affairs
2-2-1
Kasumigaseki, Chiyoda-ku
Tokyo
Tel: 03 (5501) 8344 (Direct)
International: + (81) 3 3580 3311
Fax: 03 (6402) 2203
International: + (81) 3 5501 8343

Official Testing Laboratories

Guidance for Foreign Official Laboratories

<http://www.mhlw.go.jp/english/topics/importedfoods/dl/1-10.pdf>

Listing of MHLW registered laboratories in the United States

<http://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf>

Listing of MHLW registered laboratories in Japan.

(Please note that the list is an Excel spreadsheet in Japanese; however, it also contains the laboratory name and phone number in English.)

<http://www.mhlw.go.jp/english/topics/importedfoods/1-10.html>

Imported Food Inspection Services (Section 11 also contains a list of foreign registered laboratories.) <http://www.mhlw.go.jp/english/topics/importedfoods/index.html>