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Global Agricultural Information Network

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Japan

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

Updated Sections: I. Food Laws; II. Labeling Requirements; IV. Food Additives Regulations; V. Pesticides and Other Contaminants; VI. Other Regulations and Requirements; VII. 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 preparation of this report, 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.

Section I. 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 Health Promotion law.

The Food Safety Basic Law set the principles for developing a food safety regime and also set up the role of the Food Safety Commission, 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 following Japan External Trade Organization (JETRO) website:

<http://www.jetro.go.jp/en/market/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 procedure may be viewed on the MHLW 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. 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. Another option is to have a sample of the product tested by an official MHLW registered laboratory in the United States. A full list of the registered laboratories can be found on the following MHLW website: <http://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf>.

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 animal and plant health protection through a series of quarantine laws. 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:

<http://www.maff.go.jp/e/jas/specific/organic.html>.

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 the following JETRO website: <http://www.jetro.go.jp/en/market/regulations/index.html>.

Information on the Japanese organic standards, with background on the export agreements with Japan, is available on the USDA/Agricultural Marketing Service (AMS) website ([Export Arrangements with Japan](#)).

Section II. Labeling Requirements:

Labeling Required by Japanese laws

The JAS law and Food Sanitation Law require that the label on retail packages for imported food products should include the following information, in Japanese:

- Name of the product;
- Country of origin;
- Name 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, biotech food labeling has been handled by Japan’s Consumer Affairs Agency. However, the regulation and its implementation have not changed substantially. For more information on biotech labeling, please refer to the websites below.

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

MAFF: <http://www.maff.go.jp/e/jas/labeling/modified.html>

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

Please note that the United States is no longer commercially producing biotech potatoes. Therefore, IP handling is not required for non-biotech U.S. potatoes until the point where the adventitious presence of biotech potato can be suspected, e.g. until the arrival at Japanese ports. As of December 2010, exporters

who follow the MAFF's JAS biotechnology-labeling scheme described later in this report will also be considered to have met the MHLW labeling regulations.

- Place of origin for all perishable foods (produce, meat, seafood, and dairy); see “Labeling Fresh Foods” under “Labeling” on the following MAFF website: <http://www.maff.go.jp/e/jas/labeling/fresh.html>.
- 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/jas/specific/organic.html>.
- Note there are 50 processed foods, which have additional Individual Quality Labeling Standards. There is no English translation available, but details can be found on the following MAFF website: http://www.maff.go.jp/j/jas/hyoji/kijun_itiran.html.
- Allergen labeling; required by Consumer Affairs Agency (CAA; formerly required by MHLW) on foods containing any of the seven ingredients known to cause significant allergic reactions: wheat, buckwheat, egg, milk, peanuts, prawn and crab. CAA also recommends that any possible additional allergens be listed on the label when present in the food: abalone, squid, salmon roe, orange, kiwi fruit, beef, walnuts, salmon, mackerel, soybean, chicken, pork, Matsutake mushrooms, peach, yam, apple, banana, and gelatin. For details, please see the CAA website: <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.

Pharmaceutical Products and Supplements

- To comply, the importers must submit to MHLW an application for approval to import. The application must be submitted through the Tokyo Metropolitan Government Office or local prefecture government office, depending on the location of the importer. The local government office, or MHLW if necessary, reviews the pharmaceutical products for approval based on the application, which must include effectiveness data, on a case-by-case basis.
- In addition, a company without a license to handle pharmaceutical products and/or cosmetics cannot market this class of product. Therefore, interested companies should request more detailed information on the application procedures from MHLW through the importer.

Nutritional Labeling

While nutritional labeling is voluntary in Japan, CAA requires food manufacturers to provide nutritional information on the label under the Health Promotion Act. The U.S. nutritional fact panel is not acceptable, as nutritional labeling must be in Japanese. If a company includes any nutritional information (e.g., vitamin content), then all five major nutritional facts about the food must be included. These 5 items are:

- 1) calories (kilo calories);

- 2) protein (grams);
- 3) fat (grams);
- 4) sugar or carbohydrate (gram);
- 5) sodium (milligrams or grams in cases above 1,000 mg).

In addition to the required five nutritional facts, 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: <http://www.caa.go.jp/en/pdf/syokuhin569.pdf> .

- For dietary fiber, protein, calcium, iron, Vitamin A, Vitamin B1, Vitamin B2, niacin, Vitamin C and Vitamin D, health-related claims such as “rich in” or “containing” must meet minimum content level standards required by the Health Promotion Act. Claims that include the terms “less” or “no” in regards to calories, fat, saturated fatty acid, sugar or sodium, must also meet maximum content standards required by the Health Promotion Act. For example, when a “no sodium” or “low or less sodium” claim is made, the sodium content must be lower than 5 mg and 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 3 g per 100 g of food, respectively.

For more details on content level standards, please see the CAA website:

<http://www.caa.go.jp/foods/pdf/syokuhin90.pdf> . Please note that this document is in Japanese.

- Japan has strict rules on functional and nutritional claims. 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 Consumer Affairs Agency 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>.

Section III. 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/market/regulations/> (see “Specifications and Standards for Foods, Food Additives, etc., Under the Food Sanitation Law”)
- Japan Food Chemical Research Foundation (FFCR):
<http://www.ffcr.or.jp/zaidan/ffcrhome.nsf/TrueMainE?OpenFrameSet>.
- Private industry is required to pay all costs associated with recycling. For imported products, part of the recycling cost is borne by importers. However, some Japanese importers may ask their suppliers overseas to cooperate in supplying the additional labeling. Importers are responsible for making sure that there are appropriate labels on all packaging and containers used for imported goods. 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 IV. Food Additives Regulations:

- Additives, both artificial and natural, that are not approved are banned from use in Japan, and imports of product found to contain residues from unapproved additives will not be allowed for sale in Japan. While CODEX standards are considered in MHLW’s safety assessment, only additives that have been reviewed by the Food Safety Commission and approved by MHLW may be used in foods and beverages sold in Japan.
- An approved additive may be limited to use on a specific product at a set level and only permitted for specific use. For a full list of approved additives, approved uses, and tolerances, please refer to MHLW’s “Food Additive” website <http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html> and the following FFCR website: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/stanrd.use> (please note the pdf file for the ‘Table of Standards for Use, according to Use Categories’).
- Though there are no substantial changes in the regulation and its practice, the labeling of food additives, including post harvest fungicides, are handled by CAA. For details, please refer to the following website: <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 having 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 will review applications for the approval of new food additives and the approval of new uses and tolerances for additives that have been approved previously. Though MHLW is the contact point for the application, after the completeness check, the application is sent to FSC for the risk assessment of the substance. After completion of the risk assessment, 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 average daily intake (ADI) of the substance. 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 pickles, depending on the scope of the food category which the application covers. For the additive to be approved for use on pickles, an applicant would have to supply MHLW with the relevant technical data to demonstrate that the additional use would not result in unacceptable daily intake levels. 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 from Appendix 5 of the following FFCR document: [http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/PDF/\\$FILE/Guideline.pdf](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/PDF/$FILE/Guideline.pdf).

Section V. 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. After a risk assessment is completed, an official MRL can be established. 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 two violations of a specific MRL, the product could be subject to a costly Inspection Order, 100 percent hold and test measures, which could involve lengthy delays at the port. In order to return to normal monitoring status following a single violation, MHLW requires a clean record of 60 tests or one year with no further violations. Following multiple violations, MHLW requires 300 clean test records and two years with no further violations before removing an Inspection Order (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>).

Also, 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 (<http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/dl/r04.pdf>). For a comparison of U.S. and Japanese MRLs, please visit the following site: <http://www.mrlatabase.com/>.

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

Other information in English about the positive list system, including the actual MRLs, can be found on MHLW's 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 tests 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% 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 FY2012 monitoring plan can be found at the following website:

http://www.mhlw.go.jp/topics/yunyu/kanshi/h24/yunyu_keikaku_en.html.

(For the pdf version: http://www.mhlw.go.jp/topics/yunyu/kanshi/h24/dl/yunyu_keikaku_en.pdf)

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

The interim report of FY2011 inspection results can be found at the following website:

<http://www.mhlw.go.jp/english/topics/importedfoods/11/11-06.html>.

Establishment of MRLs for Agrochemicals

In order for an agrochemical to receive an official MRL, concerned parties must submit an application to MHLW, which will go through an extensive review process, including a risk assessment by the Food Safety Commission (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: <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.

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 items tested in the past.

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 “Implementation of ‘Imported Foods Monitoring Plan for FY 2012’”, which can be found at <http://www.mhlw.go.jp/english/topics/importedfoods/12/notice-2012-0329-02.html>.

Section VI. Other Regulations and Requirements:

Food import procedure under the Food Sanitation Law is described on the following MHLW website: <http://www.mhlw.go.jp/english/topics/importedfoods/1.html>.

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 the manufacturing process. Your importer will be able to guide you regarding the detail needed for these documents.

Bovine free certification

Processed foods that could possibly contain ingredients from ruminants, such as gelatin, must certify 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](#).

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 VII. Other Specific Standards:

Biotechnology Foods

The Government of Japan (GOJ) requires an environmental and food safety assessment of biotech products before they can be exported to Japan. No foods or beverages or their ingredients may contain "materials" produced through recombinant DNA techniques that have not been approved by the GOJ. As of December 6, 2012, Japan has approved 191 biotech 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 biotech 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 beet and cotton. 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 GOJ. Any shipment

found to contain an unapproved variety may not be imported into Japan.

MAFF also conducts mandatory environmental safety assessments as required by the Biosafety Protocol. MAFF performs feed safety assessments (where appropriate) for biotechnology products.

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

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 [JA2013](#).

Please note that the United States is no longer commercially producing biotech potatoes.

Meat and Meat Products

Fresh, prepared, or preserved meat and meat products going into Japan from the United States must be accompanied by U.S. Department of Agriculture, 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 following FSIS Export Library webpage: http://www.fsis.usda.gov/Regulations & Policies/Japan_Requirements/index.asp.

Beef going into Japan is currently operating under the Export Verification Program (EV) due to BSE findings in the United States. Under this program, all beef sent to Japan must be from cattle slaughtered at 20 months of age or below and the meat must be from the facilities audited and approved by the Agricultural Marketing Service (AMS). The official listing of eligible suppliers in the EV Program for Japan and a description of the specific requirements can be found on the AMS website ([LS Japan EV Program](#)).

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, cabbage, chilies, eggplant, peaches, pears, potatoes, radishes, sweet potatoes and yams. For more information, contact the Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine, Export Services, 4700 River Road, Unit 140, Riverdale, MD 20737-1228, (301) 734-8537.

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 self-certified by the U.S. processor, exporter or state department of agriculture. Self-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

Section VIII. Copyright and/or Trademark Laws:

International trademarks are not protected in Japan. Trademarks must be registered at the Patents, Trademarks and Licensing Office in Japan. The first applicant for a trademark is entitled to its registration.

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 Quarantine Station, Ministry of Health, Labor, and Welfare. 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.

Details of food importing procedures may be viewed at the following MHLW website:

<http://www.mhlw.go.jp/english/topics/importedfoods/1.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 providing product samples to:

Customs Counselor's Office

(ZEIKAN SODANKAN SHITSU)

Tokyo, Customs Office
5-5-30, Konan, Minato-ku
Tokyo
Tel: 81-3-3472-7001

Labeling Regulations and Health Standards are administered by:

Standards and Evaluation Division
Ministry of Health, Labor, and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo
Tel: 81-3-3595-2341
Tel: 81-3-3501-4868

Additional Assistance can be obtained by contacting:

Agricultural Affairs Office
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:

First International Organization Division
Economic Affairs Bureau
Ministry of Foreign Affairs
2-2-1
Kasumigaseki, Chiyoda-ku
Tokyo
Tel: 03 (3580) 3311
International: + (81) 3 3580 3311

Fax: 03 (6402) 2203

International: + (81) 3 5501 8343