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Japan

Food and Agricultural Import Regulations and Standards (FAIRS) Report 1998

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Report Highlights:

The FAIRS report provides a guide to Japan's import regulations and standards.

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Includes PSD changes:

Includes Trade Matrix:

DRAFT**JAPAN: FOOD IMPORTS REGULATIONS AND STANDARDS****Last Updated: July 1998****Section(s) Last Updated: NEW**

DISCLAIMER: This report has been prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in (Tokyo, Japan) for U.S. exporters of food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may no longer be complete nor precise, as some import requirements are subject to frequent change. It is highly recommended that U.S. exporters ensure that all necessary customs clearance requirements have been verified with Japanese authorities through your foreign importer before the sale conditions are finalized. FINAL IMPORT APPROVAL OF ANY PRODUCT IS ALWAYS SUBJECT TO THE RULES AND REGULATIONS AS INTERPRETED BY THE COUNTRY OF IMPORT AT THE TIME OF PRODUCT ENTRY.

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A. FOOD LAWS

The Food Sanitation Laws were established by the Japanese government to ensure the safety and sanitation of foods. The law prohibits the sale of foods containing poisonous or harmful substances. It prescribes the standards which foods, additives and food apparatus and container packages must meet. These regulations apply to all foods imported to Japan. **Imported foods which do not meet these requirements will not be allowed entry.** The general requirements and standards are set by the **Japanese Ministry of Health and Welfare (MHW)** and cover all types of foods. These requirements and standards place primary emphasis on component requirements and manufacturing standards. It is strongly recommended that in the event that a product label does not clearly indicate additives, preservatives, coloring material, spices or flavorings, etc. that a certificate with detailed descriptions of the ingredients (i.e., the names of chemical compounds, chemical names and international index numbers on the colors, etc.) should be attached to each shipment in order to expedite import procedures.

Before shipping a new or unknown product to Japan, MHW suggests that the Japanese importer deliver a small sample of the product to be imported to the MHW port inspectors office with a certificate certifying compliance with required product regulations. These samples should be inspected to insure that no importation problems exist before the product is actually 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 one of the MHW official or registered laboratories located in the U.S. (listed later in this report).

Food Sanitation Law

In Japan, foods, additives, apparatus, container-packages and certain toys are regulated from the viewpoint of sanitation by the Foods Sanitation Law which is under the jurisdiction of the Ministry of Health and Welfare. The purpose of this law is to protect the people from health hazards which may be caused by eating or drinking, and to help improve and promote public health. The law is therefore applicable to imported foods, etc., as well as to domestic products.

The law prohibits the production, importation, or sale of unsanitary foods and those not complying with the prescribed standards, etc. The following is an outline of the principal provisions of the law concerned with such standards:

1. Food or food additives which are rotten or decomposed, contain poisonous or detrimental substances, contaminated with pathogenic microorganisms or contain foreign substances (Article 4).
2. Newly developed novel foods which may be prohibited from sale by the Minister of Health and Welfare after consultation with the Food Sanitation Investigation Council (Article 4-2).
3. Meat of diseased or dead livestock (Article 5).
4. Apparatus or container-packages containing poisonous or harmful substances (Article 9).

The law prohibits the production, import or sale of unsanitary foods, foods not conforming with established standards of manufacturing, preservation of ingredients, and apparatus and container-packages not meeting prescribed specifications and standards.

The law also requires the importers of foods, etc. to submit import notification to the quarantine station.

B. LABELING REQUIREMENTS

All food products must be in perfect condition from a food sanitation standpoint. The following information must appear on the product label in the Japanese language. The minimum size of type is approximately 8 points for all characters. This should be checked by your importer.

- S Name of the product;
- S Country of origin;
- S Name of the importer;
- S Ingredients, other than additives, in descending order of weight percentage;
- S Food additives in descending order of weight on a separate line from other ingredients;
- S The net weight in metric units only. A system of average net weight tolerances of packages or certain commodities are set by the Ministry of Health and Welfare;
- S “Best-before date” or “Expiry of consumption” on products whose quality changes rapidly;
- S Method of use, storage instructions, or preparation, when laid down by the Minister of Health and Welfare for the product or when its absence could cause confusion.

Pharmaceutical Products

It is difficult for the Japanese Ministry of Health and Welfare (MHW) to determine whether or not a product produced in a capsule and/or a product that has implied health claims can be classified as a food product without examining the actual product. However, if information on the label of product literature makes references to dosage and/or effectiveness, tablets or capsules; and the contents of pharmaceutical ingredients, etc., the product may fall into the category of pharmaceutical products or cosmetics which must comply with the Pharmaceutical Affairs Law or the Cosmetic Law for entry into Japan.

An importer must submit to MHW an application for approval for import with sufficient data including effectiveness, etc. through the Tokyo Metropolitan Government Office or the local prefectural government office, depending on the location of the importer. MHW reviews the pharmaceutical products for approval based on the overall data on a case by case basis.

Normally, it takes one year or more to have an import permit granted, depending on the products. However, since this class of product cannot be marketed by a company without a license to handle pharmaceutical products and/or cosmetics, the applicant should apply for this license to MHW directly or through the importer for more detailed information on the application procedures, as well as other aspects of the pharmaceutical products and/or cosmetics including the applicable regulations. The appropriate contact and address is as follows:

Inspection & Guidance Division and/or
Evaluation & Registration Division
Pharmaceutical Safety Bureau
Ministry of Health and Welfare
1-2-1, Kasumigaseki, Chiyoda-ku, Tokyo 100

C. FOOD ADDITIVE REGULATIONS

The Japanese operate on a positive approval system. Additives, both artificial and natural, that do not appear on the positive list of approved additives cannot be used in a food product. Restrictions on the use of a food additive is based on regulations which limit the amounts of the additive contained in the final food preparation. Many food additives which are commonly used in the United States, such as some food coloring, cannot be used in Japan, and foods containing even traces of such additives cannot be imported. In addition to the general assessment of an additive's safety, it must be approved for use in a specific product.

The Japanese Ministry of Health and Welfare (MHW) in part decides on approval of food additives based on the concept of averaged daily intake of a substance. Thus, MHW looks at the total universe of products that a certain additive is used on prior to granting approval. For example, a preservative which is approved at a certain level for margarine may not be approved as a preservative for pickles. For this particular additive to be approved for pickles, an applicant must supply the MHW with the relevant technical data which will be considered in the decision on whether or not to add pickles to the list of products on which the particular additive may be used.

The Japanese approved food additive list shows the additives that are approved for use in foodstuffs, the purpose that the additive must be used for in the product (e.g. preservative, antioxidant, etc.), the foods that the additives are allowed to be used in, and the maximum usable amounts allowed in the food. Additives must be used in the product for the purpose specified and at the set levels. To help expedite customs clearance, the following information should be provided at time of import:

...The chemical names and content in ppm (parts per million) of all synthetic additives which have tolerances levels set by MHW. Names of all natural food additives.

....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.

...Artificial flavors identified by their chemical name as they appear on the Japanese approved additive list for the specific product exported.

D. PESTICIDE AND OTHER CONTAMINANTS

Some foods have naturally occurring substances which may be considered detrimental to the human body or which may be contaminated with detrimental substances or germs during their manufacturing. Special concern has been stressed by inspection officials for the following items:

1. Aflatoxin levels in peanuts, peanut products including peanut butter, nuts, spices, some grain products;
2. Poisonous fish;

3. Shellfish poison (diarrhea poison and paralytic poison of bivalves);
4. Cyanogen (butter beans, white beans, saltani beans, etc.);
5. Methanol in distilled liquors and wines;
6. Gossypol in cottonseeds other than for oil extraction;
7. Salmonella in meat for eating uncooked;
8. Listeria in some natural cheeses;
9. Trichina in game birds, etc;
10. Radioactive substances usually in foods of European origin;
11. Decomposed or deteriorated foods of all kinds.

E. OTHER REGULATIONS AND REQUIREMENTS

U.S. Japanese Approved Laboratories:

The Ministry of Health and Welfare (MHW) has certified specific U.S. laboratories to test foods and beverages for compliance with Japan's Food Sanitation law for export to Japan. United States (U.S.) products will not need to be tested upon arrival in Japan if the shipment is accompanied by an analytical certificate from a laboratory that has been approved by MHW. The certificate issued by the U.S. laboratory must be complete and satisfactory to MHW and no additional tests for the products will be required by MHW when the product is inspected at the port of entry. The list of MHW approved U.S. laboratories is provided as APPENDIX II.

If the product is heat processed, a brief description of the production or processing method, including the temperature and length of time of heat processing, should be provided to MHW to determine compliance with Japanese manufacturing standards.

Product Containers:

These must adhere to Japanese regulations regarding size, shape, and names of materials that make up the containers. Japanese custom officials carefully inspect imported food apparatus and container packages to be sure they meet certain requirements and standards set forth in the Japanese Standards for Apparatus and Container-Packages.

Meat and Meat Products:

Fresh, prepared or preserved meat and meat products must be accompanied into Japan by U.S. Department of Agriculture, FSIS Form 9290-1 "Certificate to Export to Japan" and FSIS Form 9060-5 (formally 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. For more information, contact the Food Safety Inspection Service, Export Coordination Branch, Room 0036-South Building, Washington, D.C. 20250, (202)447-9051.

Fruits and Vegetables and Unprocessed Grain Products:

Fresh, uncooked, or partially dehydrated fruits and vegetables and unprocessed grain products must be accompanied by a USDA Phytosanitary Certificated PPQ Form 577. Certain fresh fruits and vegetables are currently prohibited under Japan's quarantine law, including apricots, bell peppers, cabbage, chillies, eggplant,

peaches, pears, plums, potatoes, radishes, sweet potatoes and yams. For more information contact the Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine, Regulatory Services Staff, 6505 Belcrest Road, Hyattsville, Maryland 20782, (301)436-8794.

Frozen Fruits and Vegetables which are permitted entry:

Those frozen fruits and vegetables which are permitted entry by the Japanese government in its 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 (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.

Frozen Fruits and Vegetables which are prohibited entry:

Those frozen fruits and vegetables which are prohibited import to Japan in their fresh (raw) state must be certified by the USDA Agricultural Marketing Service (AMS) and Form FV 146, FV 147 or FV 149 "Certificate of Quality and Condition" must accompany the product to Japan. For more information, contact AMS, Processed Products Branch, Fruit and Vegetable Division, Room 0726-South Building, Washington, D.C. 20250, (202)447-4693.

F. OTHER SPECIFIC STANDARDS

None applicable

G. COPYRIGHT/TRADEMARK LAWS

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

H. IMPORT PROCEDURE

Firms interested in importing food, food additives, container-packages or apparatus to Japan must submit a "Notification Form of Food Importation" to the Food Sanitation Inspection Section of the Quarantine Station, Ministry of Health and Welfare. The Quarantine Station will examine the product to determine if it conforms to the Japanese Food Sanitation Law, upon notification. Foods which are required to be examined will be inspected on the spot at the designated bonded warehouse. Samples will be taken and forwarded for laboratory

analysis.

Once examined and found to be in compliance with Japanese food regulations, the food is allowed entry into Japan. If the food requires no examination and is found to be in compliance with the Japanese Food Sanitation Law upon review of the Notification Form, the form is stamped.

Required Importation Documents:

Import documents required for entry into Japan are as follows:

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

Cargos found in violation of the Food Sanitation Law are re-shipped, destroyed or otherwise disposed of.

In addition, various other documents should be prepared depending on case:

Foods, etc.	Accompanying Documents	Remarks
Meat and viscera of animals (cattle, horses, pigs, sheep, goats and water buffalo) and poultry and products manufactured from these items.	A sanitation (health) certificate on inspection results, which is issued by a government organization of the exporting country.	Mandatory (Food Sanitation Law, Article 5, 2)
Shellfish	A sanitation (health) certificate including information on species of fish, sea area of fishing, etc., which is issued by an official organization of the exporting country.	Mandatory (E.V. Notice No. 7 of March 3, 1984)
Large Peanuts	A certificate showing negative results of an aflatoxin test, which is issued by a government or official organization of the exporting country.	If such a certificate is not submitted, an aflatoxin test will be conducted when imported. (E.F. Notice No. 311 of June 18, 1971)

3. Other Documents - For processed foods which are imported for the first time, documents containing more detailed information on raw materials and ingredients, manufacturing process, etc. than those stated in the

import notification should be attached.

APPENDIX:

APPENDIX I -

The following are names and address of offices you can contact to receive detailed information on regulations and requirements to import to 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 imports quotas could be obtained by 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 are administered by:

Food Chemistry Division
Ministry of Health and Welfare
1-2-2, Kasumigaseki, Chiyada-ku
Tokyo
Tel: 81-3-3595-2341

Health Standards are administered by:

The Food Sanitation Division
Ministry of Health and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo
Tel: 81-3-3595-2326

Additional Assistance can be obtained by contacting:

Agricultural Affairs Office
U.S. Embassy
UNIT 45004, Box 226
APO AP 96337-0001
Tel: 81-3-3224-5102
Fax: 81-3-3589-0793

Laboratory Certification:

The certificate issued by the U.S. laboratory must be satisfactory to MHW and no additional tests for the products will be required by MHW when the product is inspected at the port of entry. Tests, including microbiological tests, for substances for which levels may change during storage and/or transit will not be acceptable to MHW. A certificate issued by another laboratory or manufacturer may also be taken into consideration to some extent by MHW for clearance purposes. The U.S. approved laboratories are as follows:

Official Laboratories

Oregon Department of Agriculture Export Service Center Suite 320 Albers Mill Building 1200 NW Front Ave., Portland, Oregon 97209-2898 Phone: (503) 229-6557 Fax: (503) 229-5933	California Department of Food And Agricultural Chemistry Laboratory Service 3292 Meadowview Road Sacramento, CA 95832 Phone: (916) 262-1549 Fax: (916) 262-1572
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Registered Laboratories

Cargill Analytical Services Neosho Laboratory Crowder Industrial Park 4301 Doniphane Drive Neosho, MO 64850 Phone: (417) 451-5973 Fax: (417) 451-5478	Midwest Research Institute 425 Volker Blvd. Kansas City, Missouri 64110 Phone: (816) 753-7600 Fax: (816) 753-8420
OMIC USA Inc. 1200 N.W. Front Avenue, Suite 100 Portland, Oregon 97209 Phone: (503) 224-5929 Fax: (503) 223-9436	ABC Research Corporation 3437 SW 24 th Avenue Gainesville, Florida 32602 Phone: (904) 372-0436 Fax: (904) 378-6483
Michelson Laboratories 6280 Chalet Drive Commerce, CA 90040 Phone: (310) 928-0553 Fax: (310) 927-6625	Bolin Laboratories, Inc. 17631 N. 25 th Avenue Phoenix, Arizona 85023 Phone: (602) 942-8220 Fax: (602) 942-1050
Columbia Laboratories, Inc. 36740 East Crown Point Highway P.O. Box 40 Corbett, Oregon 97019 Phone: (503) 695-2287 Fax: (503) 695-5187	Food Products Laboratory, Inc. 12003 NE Ainsworth Cir., Ste 105 Portland, OR 97220-1099 Phone: (503) 253-9136 Fax: (503) 253-9019

West Coast Food Center 12423 NE Whitaker Way Portland, Oregon 97230 Phone: (503) 254-5143 Fax: (503) 254-1452	Acts Testing Labs, Inc. 25 Anderson Road Buffalo, NY 14225-4928 Phone: (716) 897-3300 Fax: (716) 897-0876
C.L. Technology, Inc. 280 North Smith Ave. Corona, CA 91720 Phone: (909) 734-9600 Fax: (909) 734-2803	Silliker Laboratories of Illinois, Inc. 1304 Halsted Street Chicago Heights, IL 60411 Phone: (708) 756-3210 Fax: (708) 756-2898
Primus Laboratories 3130 Skyway Dr. Suite 308 Santa Maria, CA 93455 Phone: (805) 922-0055 Fax: (805) 922-2462	The National Food Laboratory, Inc. 6363 Clark Avenue Dublin, California 94568-3097 Phone: (510) 828-1440 Fax: (510) 833-8795
Irvine Analytical Laboratories, Inc. 10 Vanderbilt Irvine, CA 92618 Phone: (714) 951-4425 Fax: (714) 951-4909	

Wine and Wine Products

Canandaigua Wine 116 Buffalo Street Canandaigua, NY 14424-1086	ETS Laboratories 899A Adams Street St. Helena, CA 94574
Ernest and Julio Gallo P.O. Box 1130 Modesto, CA 95353	Canandaigua Wine Co., Inc. Mission Bell Winery 12667 Road 24 P.O. Box 99 Madera, California 93639
Heublein, Inc. 430 New Park Avenue West Hartford, Connecticut 06110-1142	Fetzer Vineyards, Inc. 1150 Bel Arbres Road P.O. Box 227 Redwood Valley, CA 95470
Scott Laboratories, Inc. P.O. Box 4559 Petaluma, California 94955-4559	Sebastiani Vineyards P.O. Box 1290 Woodbridge, California 95258

Columbia Crest Stimson Lane, Ltd. Highway 221, 1 Mile North of Paterson P.O. Box 231 Paterson, Washington 99345-0231	Vinquiry P.O. Box 695 16003 Healdsburg Avenue Healdsburg, California 95448
Vintners International Company, Inc. A division of Canandaigua Wine Company, Inc. 800 South Alta Street P.O. Box 780 Gonzales, California 93926	Wine World Estate 2000 Main Street P.O. Box 111 St. Helena, California 94574
Silverado Vineyards 6121 Silverado Trail Napa, CA 94558	Sutter Home Winery, Inc. P.O. Box 248 St. Helena, California 94574
Glen Ellen Winery-Carneros 21468 8 th Street East Sonoma, California 95476	Robert Mondavi Winery P.O. Box 106 Oakville, California 94562
Northwest Wine Consultants 509 Merclyn Lane Zillah, Washington 98953	The Wine Group Inc. 17000 East Highway 120 P.O. Box 897 Ripon, California 95366
Beaulieu Vineyard 1960 South St. Helene Highway Rutherford, California 94573	Brown-Forman Beverages Worldwide 850 Dixie Highway (40210) P.O. Box 1080 Louisville, Kentucky 40201
Mumm Napa Valley 8445 Silverado Trail Napa, California 94558	Mogen David Wine Corporation 85 Bourne Street Westfield, New York 14787
Joseph. E. Seagrams & Sons, Inc. Westchester Technical Center 103 Corporate Park Drive White Plains, NY 10604-3877	Golden State Vintners 38558 Road 128 P.O. Box 39 Cutler, CA 93615
Parducci Wine Cellars 501 Parducci Road Ukiah, CA 95482	Nyssa Analytical Laboratories 3850 Ramada Dr., Suite D5 Paso Robles, CA 93446

Distilled Spirits

Barton Brands, Ltd. Barton Road P.O. Box 788 Bardstown, KY 40004	Jim Beam Brands, Co. Highway 245 Clermont, KY 40110
Heublin, Inc. 430 New Park Ave. Hartford, CT 06110-1142	Grain Processing Corporation 1600 Oregon Street P.O. Box 349 Muscatine, Iowa 52761-0349
Joseph E. Seagram & Sons Westchester Technical Center 103 Corporate Park Drive White Plains, NY 10604-3877	Vinquiry, Inc. 16003 Healdsburg Avenue P.O. Box 695 Healdsburg, CA 95448
United Distillers Production, Inc. 3860 Fitzgerald Road (40216) P.O. Box 740010 Louisville, KY 40201-7410	Brown-Forman Beverages Worldwide 850 Dixie Highway (40210) P.O. Box 1080 Louisville, Kentucky 40201
E. & J. Gallo Winery P.O. Box 1130 Modesto, California 95353	Leestown Co., Inc. 1001 Wilkinson Blvd. Frankfort, KY 40601

APPENDIX II - WORLD TRADE ORGANIZATION (WTO) INQUIRY POINT

Each member government is responsible for the notification procedures associated with agreement under the World Trade Organization (WTO). Examples here relate to the Sanitary, PhytoSanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. WTO obligations include notifying any trade significant proposals which are not substantially the same as international standards to the WTO; providing copies of the proposed regulation upon request; allowing time for comments; and also to provide upon request copies of other relevant documents on existing regulations related to food and agriculture. Information on the country's regulations, standards and certification procedures can also be obtained through the Inquiry Point(s) listed below:

(a) Standards Information Service

First International Organization Division
Economic Affairs Bureau
Ministry of Foreign Affairs
2-2-1
Kasumigaseki, Chiyoda-ku
Tokyo

Telephone: 03 (3580) 3311
International + (81) 3 3580 3311

Telex: C.J22350

A. GAIMU A-B J22350

Telefax: (03) 3503 3136
International + (81) 3 3503 3136

(b) Standards Information Service
Information Service Department
Japan External Trade Organizations (JETRO)
2-2-5
Toranomom, Minato-Ku
Tokyo

Telephone: 03 (3582) 6270
International + (81) 3 3582 6270

Telex: C. J24378
A. JETRO A-B J24378

Telefax: 03 (3589) 4179
International + (81) 3 3589 4179

In relation to the services of these two bodies, a Standard Agreement Office has been established in the Ministry of Foreign Affairs (MOFA).

Inquires can be made in a GATT language.