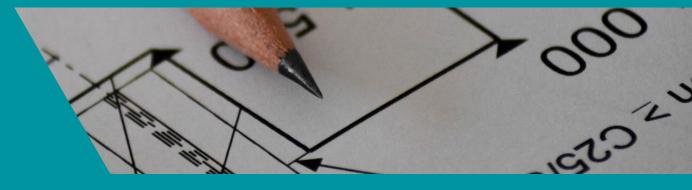




Machinery & Equipment

Product requirements in Japan under the EU-Japan EPA



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1. Overview

1.1 Tariff Rates

• For more detailed information on tariff rates please refer to My Trade Assistant

1.2 Environmental Regulations which apply to Imported Goods in General

- 1.2.1 Labelling Requirements Prescribed under the Act on the Promotion of Effective Utilization of Resources
- Ministry of Economy, Trade and Industry (METI): <u>Description of the Act on the Promotion of</u> Effective Utilization of Resources (Japanese)
 - Description of the requirement to put an identification mark on paper and plastic containers/packages which indicates that those containers/packages are made of paper or plastics that is recyclable.
- Act on the Promotion of Effective Utilization of Resources (English and Japanese)
 - The English translation at the above link is outdated. The latest text is available only in Japanese.
 - 1.2.2 Requirement to Recycle Containers/Packages Made of Paper, Plastic, PET, or Glass
- METI: <u>Description of the Act on the Promotion of Effective Utilization of Resources</u>. You can find further information <u>here</u> (Japanese)
 - Description of the requirement to recycle paper, plastic, PET, or glass containers/packages imposed on enterprises (which meet the thresholds for turnover or number of employees, and which import these containers/packages or use these containers/packages when they sell their products). These entities can also fulfill their obligations by paying commissions to the Japan Containers and Packaging Recycling Association, which is a public interest incorporated foundation.
- Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging (<u>English</u> and <u>Japanese</u>)
 - The English translation at the above link is outdated. The latest text is available only in Japanese.

2. Consumer Electronics

2.1 Procedures for Importation into Japan

- Manufactured Imports and Investment Promotion Organisation (MIPRO): <u>2018 Guidelines for Importing Consumer Electronics</u> (Japanese)
- Japan Customs: Re-Exportation of Machinery and Equipment after Repair in Japan (Japanese)

2.2 Display of Information regarding Safety on the Surface of Products (i.e., Precautions regarding Use and Expected Life of the Product)

- Ministry of Economy, Trade and Industry (METI): Electrical Appliances and Materials Safety Act Statutory Operations Implementation Guide For Manufacturers/Importers (<u>Version 3 English</u>, <u>Version 4 Japanese</u>)
 - o The latest edition is available only in Japanese.
 - Exporters of electrical appliances are not required to submit a notification of business or to ensure electrical appliances' conformity with the technical requirements contained in the Electrical Appliances and Materials Safety Act; instead, this responsibility falls to the domestic manufacturers and importers of such appliances.
- Electrical Appliances and Materials Safety Act (English and Japanese)
 - The English translation at the above link is outdated. The latest text is available only in Japanese. An overview of the act is also available on the METI website (English)
- METI: <u>Trade and Investment Q&A Display of information regarding safety on the surface of products</u> (Japanese)
 - This information does not have to be affixed to the products at the time of importation.
 However, displaying the required information is a necessary prerequisite for distribution of the products in Japan.

3. Cookware

3.1 Cookware that is also an Electronic Appliance

- 3.1.1 Labelling Requirement Prescribed under the Act on the Rational Use, etc., of Energy
- Agency for Natural Resources and Energy METI: <u>Description of the labelling showing whether</u> the product meets the "Top-Runner" standards (Japanese)
 - Article 147 of the Act on the Rational Use etc. of Energy imposes an obligation on manufacturers of "Energy-Consuming Equipment" (designated under Article 18 of the Ministerial Order of the Act on Rationalizing Energy Use, including rice cookers and cookware using gas energy) to display the energy consumption efficiency of the product.
- Act on the Rational Use, etc., of Energy (English and Japanese)
 - The English translation at the above link is outdated. The latest text is available only in Japanese.
- 3.1.2 Permission from the MIC Minister (Microwave Heaters or IH Cooking Heaters)
- Ministry of Internal Affairs and Communications (MIC): <u>Procedures for exemption from the requirement to obtain certain permissions from the Minister of Internal Affairs and Communications</u>
 - Permission from the MIC Minister is required when microwave heaters or IH cooking heaters which fall under the category of Equipment Utilizing High Frequency Currents, as defined under the Radio Act, are installed, unless the manufacturer or importer has confirmed the conformity of the heaters with the Radio Act and has submitted a report of such confirmation to the MIC Minister.
- Radio Act (<u>English</u> and <u>Japanese</u>)
 - The English translation at the above link is outdated. The latest text is available only in Japanese
- MIC: <u>Enforcement Regulations of the Radio Act</u> (Japanese)
- 3.2 Import Procedures under the Food Sanitation Act
- MHLW: <u>Import Procedure under Food Sanitation Act</u> (English)

- MHLW: Notification Form for Importation of Foods, etc. (English)
- MHLW: <u>Import procedures</u> (Japanese)
 - The <u>import notification form</u> for submission to the quarantine information office is available in Japanese
- Food Sanitation Act (<u>English</u> and <u>Japanese</u>)
 - The English translation at the above link is outdated. The latest text is available only in Japanese.

3.3 Standards for Chemicals/Additives

- MHLW: <u>Draft Positive Lists</u> of the chemicals and additives which are to be allowed to be contained in cookware and packaging of food products sold in Japan (Japanese, partially English)
- More information in English can be found here on the amendment of Food Sanitation Act and the
 Positive List. Within that file a link is provided to the draft positive lists in excel (available both in
 Japanese and English).
 - The notification which prescribes the positive lists is scheduled to be published in February 2020, and the positive lists will be implemented from June 1, 2020. The Committee on the Regulation of Food Utensils, Containers, and Packaging recommended that the MHLW take a sufficient transition period for about 5 years before requiring all the relevant stakeholders to comply with the positive lists.
- For more information on the discussion in the <u>Committee on the Regulation of Food Utensils</u>, <u>Containers</u>, and <u>Packaging</u> regarding the implementation of the positive lists, please see the reference material published in Japanese by the Committee, which is disclosed with the <u>member</u> <u>list and other materials</u> (Japanese)
- MHLW: Amendment of the Food Sanitation Act (English)
- MHLW: Food Safety Information (English)
- MHLW: <u>Food Safety</u> (English)
 - (Links to laws and regulations are provided under the Acts and Regulations section.)
- MHLW: <u>Utensils</u>, <u>Containers and Packaging</u> (English)
- MHLW: Report by the Committee on the Regulation of Food Utensils, Containers and Packaging (June 16, 2017) (English)
- MHLW: <u>The summary of the amendment to the Cabinet Order and Ordinance for Enforcement of the Food Sanitation Act</u> (2018) (English)

- MHLW: Guideline for safety assurance in the manufacture etc. of food utensils, containers and packaging (July 10, 2017) (English)
- MHLW: Specifications and Standards for Food, Food Additives, etc. (Ministry of Health and Welfare Notification No. 370, 1959) > <u>Utensils, Containers, Packaging, Toys</u> (English)
- MHLW: Introducing the positive list to cookware and food containers (August 2019) (Japanese)
- JETRO: <u>Trade and Investment Q&A How to import cookware into Japan</u> (Japanese)

4. Medical Devices

4.1 Accreditation of Foreign Manufacturers

- Japan Customs: Customs Answer 1805 Customs confirmation requirement concerning import restrictions in accordance with the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics Law (English)
- Pharmaceuticals and Medical Devices Agency (PMDA): <u>Accreditation of Foreign Manufacturers</u> (English
- JETRO: Trade and Investment Q&A How to import medical devices into Japan (Japanese)
- Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (<u>English</u> and <u>Japanese</u>)
 - The English translation at the above link is outdated. The latest text is available only in Japanese.

4.2 Medical Device Marketing Approval Reviews

- PMDA: Medical Device Reviews (English)
- PMDA: <u>Third-Party Evaluation</u> [Required for Obtaining Marketing Approval of High-Risk Medical <u>Devices</u>] (Japanese)