Handbook for Consumer Products Import Regulations 2010

October 2010

JETRO Japan External Trade Organization

Contents

I. FASHION	2
I-1. Leather Footwear	
I = 2. Eyewear	
I = 3. BAGS	
${\rm I\hspace{-1.5pt}I}$. INTERIOR AND HOUSEHOLD GOODS	5
II – 1. Carpets	
II – 2. TABLEWARE	
II -3 . Gas Lighters	
II - 4. Toys	
III. VEHICLES, ETC	10
III-1. BICYCLES	
III – 2. MOTORCYCLES	
III – 3. Helmets	
III – 4. PASSENGER VEHICLES	
III -5 . Yachts and Motorboats	
IV. HEALTH AND BEAUTY	20
IV-1. COSMETICS	
IV-2. AROMA PRODUCTS	
IV – 3. HARBAL AND NATURAL MEDICINES	
V. HOBBIES	
V – 1. Musical Instruments	
V – 2. MOUNTAINEERING EQUIPMENT	
V-3. VIDEO SOFTWARE	
VI. OTHER	
VI-1. WHEELCHAIRS	
VI-2. Cribs	
₩. OUTLINE OF RELEVANT LAWS	
${ m MI-1}$. Act against Unjustifiable Premiums and Misleading Representation	ONS
${ m VII}-2$. Act on the Promotion of Sorted Collection and Recycling of Cont	
ACT ON THE PROMOTION OF EFFECTIVE UTILIZATION OF RESOURCES	
WI-3. INDUSTRIAL STANDARDIZATION ACT (JIS MARK LABELING SYSTEM)	
M = 4. Household Goods Quality Labeling Act	
M-5 . Act on Control of Household Products Containing Harmful Subs	
WI-6. Electrical Appliances and Material Safety Act	
VII – 7. CONSUMER PRODUCT SAFETY ACT	

I. Fashion

I – 1. Leather Footwear

Leather footwear (HS 6403 - 6405) is subject to the Tariff Quota (TQ) System.

1. Customs Tariff Law (Tariff Quota)

Under the Ministerial Ordinance on the Tariff Quota (TQ) System, a lower tariff rate (primary rate) is assessed on quantities of imports within the limits of the annual tariff quota and a higher tariff rate (secondary rate) is assessed on imports in excess of that quota.

Methods of applying for a tariff quota certificate are announced by the Ministry of Economy, Trade and Industry (METI) and the Regional Bureau of Economy, Trade and Industry.

2. Import Trade Control Order (CITES)

Products made from wild flora and fauna regulated under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES, Washington Convention) require certification such as an export certificate or a certificate of origin issued by an agency of the government of the exporting country and an import authorization issued by the Minister of Economy, Trade and Industry showing that importation of the product is not prohibited, based on the categories of the appendices to the Convention. Since it is difficult to judge from general names whether an animal is subject to the Convention or has been raised as livestock, it is instructed that formal scientific names be shown on the invoices for leather products.

For products subject to Appendix I, there is a need to confirm whether the import is for purposes of academic research or is of products from plants or animals bred for commercial or non-commercial trading purposes, and whether it is an import of products acquired prior to application of the Convention, and to obtain import authorization. For products subject to Appendices II and III, if made from flora, fauna, etc. produced in countries or regions subject to strict restriction of international trading (such as prohibition of exports), there is a need to attach a copy of the export permit issued by regulators in the exporting country and to obtain prior confirmation by the MITI. If the product is not subject to prior confirmation, for products subject to Appendix II submit to customs during customs clearance the original export permit issued by regulators in the exporting country, and for products subject to Appendix III submit the original re-export certificate or certificate of origin issued by regulators in the exporting country.

Also use care concerning articles infringing on intellectual property rights (import of articles such as counterfeit brand-name goods infringing on trademark rights, design rights, etc.), products with fraudulent or mistaken labeling of origin (import of which is prohibited under the Customs Law and sale of which is prohibited under the Act against Unjustifiable Premiums and Misleading Representations).

<Useful Link>

Outline of Import Control (Ministry of Economy, Trade and Industry) http://www.meti.go.jp/english/information/data/outline.html CITES; Convention on International Trade in Endangered Species of Wild Fauna and Flora http://www.cites.org/

I - 2. Eyewear

<Sample HS classifications>:

Spectacle lenses of materials other than glass (9001.50), Frames and mountings for spectacles of plastics (9003.11), Sunglasses (9004.10), Spectacles, goggles and the like, corrective, protective or other, other than sunglasses (9004.90).

Particular care is required concerning corrective spectacles and contact lenses, since these qualify as medical devices under the Pharmaceutical Affairs Law.

1. Pharmaceutical Affairs Law

Since corrective spectacle frames and corrective lenses qualify as general medical devices (class I), a type-3 medical devices manufacturing and marketing business license is required. While there is no need for approval on a per-article basis, a notice of manufacture and sale must be submitted to the Pharmaceuticals and Medical Devices Agency.

Incidentally, since contact lenses (including fashion color contacts) qualify as specially controlled medical devices (class III), a type-1 medical devices manufacturing and marketing business license and the approval of the Minister of Health, Labour and Welfare are required for import.

2. Household Goods Quality Labeling Act

When selling subject products to ordinary consumers in Japan, labeling pursuant to the Household Goods Quality Labeling Act is required. Labeling must be affixed by the party with responsibility for the content of the labeling (e.g., importers or the seller in Japan) and the labeling must be clearly visible to and easily understandable by consumers and in the Japanese language.

Sunglasses (exclude that with corrective lenses) are required with the information of labeling required under the Miscellaneous Manufactured Goods Quality Labeling Regulations (i.e., product name, lens material, frame materials, visible ray transmission, ultraviolet ray transmission, handling precautions).

3. Other relevant laws

(1) Act against Unjustifiable Premiums and Misleading Representations

The Eyeglass Industry Fair-Trade Council has established "Fair competition code regarding labeling of eyeglasses" as autonomous industry regulations under this Act.

(2) Customs Law (articles infringing on intellectual property rights)

Import of articles infringing on intellectual property rights (i.e., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights) including counterfeit brand-name goods is prohibited. Import will be suspended even if the importer is not aware that the goods are counterfeit.

(3) CITES: Import Trade Control Order (such as tortoiseshell frame materials)

<Useful Link>

Customs confirmation requirement concerning import restrictions in accordance with the Pharmaceutical Affairs Law (Japan Customs)

http://www.customs.go.jp/english/c-answer_e/imtsukan/1805_e.htm

Pharmaceuticals and Medical Devices Agency, Japan (PMDA)

http://www.pmda.go.jp/english/index.html

Consumer Affairs Agency

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

Importing or Bringing Medication into Japan for Personal Use (Ministry of Health, Labour and Welfare) http://www.mhlw.go.jp/english/topics/import/index.html

I-3. Bags

While bags are classified under HS 4202, tariff rates vary according to materials and other factors. In particular, bags made of certain types of leather may be subject to regulation under the Washington Convention (CITES).

1. Import Trade Control Order (CITES)

While in principle importation of plant and animal species and genera subject to the Washington Convention, and of their parts and of products made from them (including bags) is prohibited, or some subjects are items to need to approval or prior confirmation by the MITI, and/or to confirmation applications or confirmation during customs clearance.

In such case, the importer being required such as an import license or confirmation issued by the MITI, an export permit, certificate of origin, re-export certificate, or processing certificate issued by regulators in the exporting country, and customs clearance is available only at certain air and sea ports.

2. Other relevant laws

(1) Customs Law (articles infringing on intellectual property rights)

Import of articles infringing on intellectual property rights (i.e., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights) including counterfeit brand-name goods is prohibited. Import will be suspended even if the importer is not aware that the goods are counterfeit.

(2) Household Goods Quality Labeling Act

Bags using cowhide, horsehide, pigskin, sheepskin, or goatskin require labeling showing the type of leather, care and storing method, and name and address or telephone number of the party responsible for labeling, under the Miscellaneous Manufactured Goods Quality Labeling Regulations.

(3) Act against Unjustifiable Premiums and Misleading Representations

Import and sale of products with fraudulent or mistaken labeling of origin is prohibited, as is sale with excessive premiums. For golf caddy bags, "Fair competition code for sporting goods labeling" have been established as autonomous industry regulations under this Act.

<Useful Link> CITES; Convention on International Trade in Endangered Species of Wild Fauna and Flora http://www.cites.org/ IPR Protection (Japan Customs) http://www.customs.go.jp/mizugiwa/chiteki/ipr_p.pdf Consumer Affairs Agency http://www.caa.go.jp/en/index.html

${\rm I\hspace{-1.5pt}I}$. Interior and Household Goods

II - 1. Carpets

Textile floor coverings such as carpets are grouped into the classification HS57, according to factors such as type of fibers used.

When fabrics or raw materials are exported from Japan and then imported in the form of textile products processed overseas within one year from the authorized export date, the Duty Reduction for Re-import system can be used to reduce import tariffs by the amount corresponding to customs tariffs on the exported raw materials, through the procedures of submitting an Application for Duty Reduction for Re-import to Customs upon export for confirmation.

1. Household Goods Quality Labeling Act

Floor coverings for household use (limited to those with piles) require labeling showing the composition of fibers, name and address or telephone number of the party responsible for labeling, and other information under the Textile Goods Quality Labeling Regulations.

2. Act on Control of Household Products Containing Harmful Substances

Sale of articles not confirming the standard values established for designated chemical substances that could be harmful to human health among chemical substances used in textiles, such as insect repellents, is prohibited.

3. Fire Service Act

Floor coverings used in facilities such as theaters and hotels must be flame retardant in satisfaction of flame-retardance standards. Articles conforming to these standards must have flame-retardance labels, and those without such labels may not be sold as flame-retardant articles.

4. Secondhand Articles Dealer Act

In some cases, handling of carpets qualifying as antiques may require a secondhand dealer's permit.

<Useful Link> Outline of the duty reduction system for re-importing processed goods (Japan Customs) http://www.customs.go.jp/english/c-answer_e/imtsukan/1605_e.htm Consumer Affairs Agency http://www.caa.go.jp/en/index.html

II - 2. Tableware

<Sample HS classifications>:

Tableware and kitchenware of plastics (3924.10), Tableware and kitchenware of wood (4419.00), Trays, dishes, plates, cups and the like, of paper or paperboard (4823.69), Tableware and kitchenware, of porcelain or china (6911.10), Ceramic tableware, kitchenware, other household articles and toilet articles, other than of porcelain or china (6912.00), Table or other household articles & parts thereof, of iron or steel (7323), Other table, kitchen or household articles and parts thereof, of copper (7418.19), Table, kitchen or other household articles and parts thereof, of aluminum (7615.19). Other customs classifications include articles of goldsmiths, or silversmiths, wares and parts thereof, of precious metal or of metal clad with precious metal (7114), Table knives having fixed blades (8211.91), and spoons and forks (8215).

1. Food Sanitation Act

When importing these products for purposes of sale or business use, Notice must be submitted to the imported food inspector of the Quarantine Station of the Ministry of Health, Labour and Welfare for the air and sea ports where the cargo clears customs by submitting the Notification Form for Importation of Foods, etc with the relevant documents attached. Import is permitted for articles judged to satisfy this law after examination and inspection.

Since under this act tableware is considered an apparatus whose standards are established concerning materials and other matters, there is a need to check conformity with these standards in advance. This applies to disposable tableware of materials such as paper and plastic as well.

While sanitary inspection by the Quarantine Station may be omitted if the importer submits documents such as results of inspection by an inspection agency designated by the Minister of Health, Labour and Welfare or an official inspection agency of the exporting country, it must be noted that "sample inspection certification system," used in past custom procedures, has been abolished - in this system, the results of inspection of articles that were imported as samples before the actual import (for purposes of sale or business) could have been submitted as that of articles actually imported.

This abolishment is due to the difficulty of confirming identification of beforehand-imported samples and articles actually imported. Thus now it is required to undergo the inspection of the actually imported articles themselves.

2. Household Goods Quality Labeling Act

Plastic tableware qualifies as "Tableware and kitchen utensils" under the Plastic Manufactured Goods Quality Labeling Regulations, and as such it requires labeling of material plastic, heat resistant temperature, and other matters. Similarly, Glass products (Tempered glass, Borosilicate glass, or Glass-ceramics) and Tableware coated with lacquer or cashew resin coating also are subject to labeling requirements under the Miscellaneous Manufactured Goods Quality Labeling Regulations (product name, type of suface painting, base material handring precautions, etc.).

Other relevant regulations that must be noted include the Act against Unjustifiable Premiums and Misleading Representations (Prohibiting acts such as exaggerated or fraudulent labeling that could mislead consumers), those concerning intellectual property rights (Prohibiting import of infringing products such as counterfeit brands), and, for disposable tableware, the Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging and the Act on the Promotion of Effective Utilization of Resources.

<Useful Link>

Customs confirmation requirements concerning import restrictions in accordance with the Food Sanitation Law (Japan Customs) http://www.customs.go.jp/english/c-answer_e/imtsukan/1802_e.htm Food Safety (Ministry of Health, Labour and Welfare) http://www.mhlw.go.jp/english/topics/foodsafety/index.html The Food Safety Commission

http://www.fsc.go.jp/english/index.html

II - 3. Gas Lighters

Import of lighters (HS 9613) requires procedures for exemption from application of the High Pressure Gas Safety Act.

1. High Pressure Gas Safety Act

In import customs clearance for aerosol products exempted from this act (e.g., spray cans, lighters, gas cartridges for portable cooker, etc.), however, a Japanese or foreign inspecting agency, or the gas lighter manufacturer who filled the product with liquefied gas, or the importer must prepare documentation of the test results and it must be confirmed that the products satisfy the requirements established in notification by the Minister of Economy, Trade and Industry. If no such documentation is submitted or the results for any item are "fail," an inspection by the competent prefectural governor (to submit the import inspection application) is required.

2. Customs Law (articles infringing on intellectual property rights), etc.

Import of articles infringing on intellectual property rights such as counterfeit character merchandise and unauthorized use of misleading names (e.g., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights) is prohibited. Under the Unfair Competition Prevention Act and other laws, import will be suspended even if the importer is not aware that the goods are in violation of the law.

Also, under the Act against Unjustifiable Premiums and Misleading Representations acts such as sale with excessive premiums and exaggerated or fraudulent labeling that could mislead consumers are prohibited.

3. Consumer Product Safety Act

In case of any serious product accident, importers of consumer products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of relevant products imported and sold, within 10 days from the day business operators including importers came to know the fact of the accident (Article 35). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents.

There have been reports of incidents such as lighters suddenly bursting into flame while placed on vehicle dashboards, fire damage from large fires ignited by lighters, etc.

The SG mark authorized by the Consumer Product Safety Association is a voluntary certification awarded to products recognized to satisfy the required standards for safe products established under the SG mark system. SG mark applies to pocket gas lighters.

4. Product Liability Act, Industrial Standards, etc.

Care also must be given to compliance with the Product Liability Act and other regulations.

The Japan Smoking Articles Corporate Association has established consumer safety standards for injection gas lighters manufactured and sold by its members (including licensed brands). It issues a "passed" seal, like the SG mark, as a product-liability guarantee to products that have satisfied its safety standards in inspection conducted by official inspection agencies.

In addition, care must be given to the fact that in some cases lighters are subject to the Fire Service Act, fire regulations, and other restrictions depending on the volume handled and their type.

<Useful Link> IPR Protection (Japan Customs) http://www.customs.go.jp/mizugiwa/chiteki/ipr_p.pdf Consumer Product Safety Association (CPSA) http://www.sg-mark.org/english/english20100810.pdf

II - 4. Toys

While in general toys are grouped in the classification HS95, in recent years matters such as functions and performance of toys have grown more varied and diverse, so that it is conceivable that relevant laws and regulations could vary by product. Only the main laws and regulations are provided below. Particular care is required concerning toys for use by infants.

1. Food Sanitaton Act

Standards and testing methods are established under this act for toys specified by the Minister of Health, Labour and Welfare (Article 78 of the Ordinance for Enforcement of the Act). Specifically, these include (i) toys which are or might be used by infants principally by putting them in their mouths (ex. Pacifier, harmonica), (ii) accessory toys (include rings, necklaces, pendants and brooches), transfer pictures, *okiagari(daruma* doll made so as to right itself when knocked over), masks, *origami*, rattles, educational toys, building blocks, toy phones, toy animals, dolls, clay, toy vehicles, balloons, blocks, balls, toys for playing house, and (iii) toys which are played with in combination with those toys listed in (ii) above. Toys not meeting these standards and testing methods may not be imported. Notice must be submitted to the imported food inspector of the Quarantine Station of the Ministry of Health, Labour and Welfare for the air and sea ports where the cargo clears customs by submitting a form of the Import Notification of Food with the relevant documents attached. Import is permitted for articles judged to satisfy this act after examination and inspection.

2. Electrical Appliance and Material Safety Law

Since many toys include electric parts, caution is required concerning whether toys are subject to this law (ex.: Toy circuit board, other toys with electronic applications).

All persons engaged manufacturing or importing electrical appliances in Japan shall notify the Ministry of Economy, Trade and Industry (Regional Bureau of Economy, Trade and Industry) of their business commencement within 30 days from the date of starting business (hereinafter referred to as a "Notifying Supplier"). The Notifying Suppliers have the obligation to secure the conformity of electric appliances and materials they import and sell to the mandatory technical standards.

The enforcement regulations to this law groups subject products into the categories of "Specified Electrical Appliances and Materials" (115 items / Category A) and "Other Electrical Appliances and Materials" (339 items / Category B). Category A products must pass the third-party conformity assessment by an inspection agency registered with national government and receive a certificate of conformity. Self-confirmation of conformity is required for Categories A and B (all regulated Electrical Appliances and Materials) whose methods are designated by the government. Also this self-inspection may be subcontracted to a registered inspection bodies. The Notifying Supplier may sell the products only after they satisfy these standards, have been subjected to inspection and other tasks, and have been labeled with the marking required such as the PSE mark, the company name, rated current, etc.

The Notifying Supplier also is required to report any serious accidents after sale of the products.

Many toys include Category A (such as transformers, electrically heater, electric vehicles, etc. for toy) as well as many Category B (such as internal components, lithium-ion batteries, etc.), and in either case advance preparations are needed.

3. Consumer Product Safety Act

In case of any serious product accident, importers of consumer products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of relevant products imported and sold, within 10 days from the day business operators including importers came to know the fact of the accident (Article 35). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents.

The SG mark authorized by the Consumer Product Safety Association is a voluntary certification awarded to products recognized to satysfy the required standards for safe products established under the SG mark system. Among products for infants, this mark applies to tricycles, foot-operated toy cars, swings, slides, and horizontal bars.

4. Industrial Regulation (ST Mark)

The ST Mark authorized by the Japan Toy Association is a voluntary certification awarded to toys recognized to satysfy the Toy Safety Standards (ST Standards). In case such as injury to a consumer due to a defect in a product with the ST Mark, compensations are paid up to a certain amount, and at the same time the seller is required to recall the product.

As part of efforts to strengthen safety measures for imported toys, which have been a topic of particular concern recently, the term of validity of the ST Mark has been shortened to two years and efforts such as shifting to new standards (ST2007) are underway.

The Japan Toy Association also certifies "the guide dog mark" and "Rabbit Mark", which signify "Universal-use toys" that give consideration to their use at ease in play with children visually or hearing impaired.

5. Other relevant laws

(1) Customs Law

Import of articles infringing on intellectual property rights (i.e., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights) including counterfeit brand-name goods is prohibited. Import will be suspended even if the importer is not aware that the goods are counterfeit. While parallel importing is not prohibited, in some cases the original rights holders apply to Customs for suspension of importing.

(2) Act against Unjustifiable Premiums and Misleading Representations

Acts such as exaggerated or fraudulent labeling that could mislead consumers are prohibited, as is sale with excessive premiums. In addition, depending on the character and function of toys (such as electric products, cameras, musical instruments, and sporting goods), it should be preferable to refer to labeling suited to the fair competition code established by individual industry groups based on this act.

(3) Household Goods Quality Labeling Act (for products which may be subject to the Textile Goods Quality Labeling Regulations)

Other laws and regulations that must be noted include those related to the Radio Act (Radio-controlled toys) and those related to recycling (such as compact secondary batteries, which may be subject to the Act on the Promotion of Effective Utilization of Resources).

<Useful Link>

Food Safety Information (Ministry of Health, Labour and Welfare) http://www.mhlw.go.jp/english/topics/foodsafety/index.html Electrical Appliance and Material Safety Law (Ministry of Economy, Trade and Industry) http://www.meti.go.jp/english/policy/economy/consumer/pse/index.html Japanese Industrial Standards Committee (JISC) http://www.jisc.go.jp/eng/index.html Consumer Affairs Agency http://www.caa.go.jp/en/index.html Consumer Product Safety Association (CPSA) http://www.sg-mark.org/english/english20100810.pdf The Japan Toy Association http://www.toys.or.jp/ IPR Protection (Japan Customs) http://www.customs.go.jp/mizugiwa/chiteki/ipr_p.pdf

Ⅲ. Vehicles, etc.

III - 1. Bicycles

While the customs classification for bicycles is HS 8712.00 (8711.90 for bicycles fitted with auxiliary motors), the parts and accessory classification (8714) checking details with the customs counselors offices is recommended.

Due to the nature of the product, in cases such as accidents resulting from defects in bicycles importers may be held liable for compensations.

1. Road Traffic Act (TS mark)

Standards are established for ordinary bicycles, bicycles fitted with auxiliary electric motors, and businesses assembling, or selling them may label the traffic safety (TS) mark certifying compliance with standards on products covered by voluntary insurance after the products have received type certification from the National Public Safety Commission. Type certification inspection is conducted by the Japan Traffic Management Technology Association.

2. Industry standard (BAA mark) / Industrial Standardization Act (JIS standards)

Bicycles certified through types testing under the bicycle safety standards of the Bicycle Association (Japan) may label the Bicycle Association (Japan) Approved (BAA) mark. However, product-liability (PL) insurance is required. Type testing is conducted by the Japan Vehicle Inspection Association and the Japan Bicycle Technical Center.

Also, since October 2008 new standards established for the purpose of reducing use of six substances with high levels of environmental impact (such as lead, mercury, and cadmium) have applied in principle to all bicycle parts.

JIS standards also include a variety of standards concerning bicycles, bicycle parts, and other related products. These include JISD9301 (bicycles for general use) and JISD9302 (bicycles for young children).

3. Consumer Product Safety Act

In case of any serious product accident, importers of consumer products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of relevant products imported and sold, within 10 days from the day business operators including importers came to know the fact of the accident (Article 35). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents. Compliance with the Product Liability (PL Law) also is required separately.

The SG mark authorized by the Consumer Product Safety Association is a voluntary certification awarded to products recognized to meet the required standards for safe products established under the SG mark system. In case of an accident due to a defect in a product with the SG mark, liability insurance is provided up to a certain amount.

- The following bicycle products and related accessories are eligible for the SG mark:
- Bicycles
- Helmets for bicycles, electric powered wheelchairs, and moving playground equipment
- Bicycle seats for children
- Bicycle air pumps

4. Other relevant laws

(1) Industrial Safety and Health Act / Foreign Exchange and Foreign Trade Act

Bicycles and parts containing asbestos may not be imported. Specifically, for safety's sake, care is required concerning abrasive materials used in bicycle clutches or brakes (i.e., clutch facings, clutch linings, brake pads, and brake linings).

Since an announcement concerning imports under the Foreign Exchange and Foreign Trade Act following enactment of the Industrial Safety and Health Act (October 2004), certification that no components including asbestos are used is required.

(2) Act on the Promotion of Effective Utilization of Resources (Bicycles fitted with auxiliary motors)

Under this act, bicycles fitted with auxiliary motors are considered Specified Reuse-Promoted Products (products for which efforts to promote the utilization of recyclable resources or reusable parts are required) and Specified Resources-Recycled Products (products using sealed batteries as components). As such, importers and sellers of these products in certain quantities (1,000 units or more) are required to carry out "three-R" (reduce, reuse, recycle) efforts.

(3) Customs Law (articles infringing on intellectual property rights), etc.

Import of articles infringing on intellectual property rights such as counterfeit character merchandise and use of misleading or unauthorized names (e.g., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights) is prohibited. Under the Unfair Competition Prevention Act and other laws, import will be suspended even if the importer is not aware that the goods are in violation of the law.

Care is also required concerning matters such as compliance with recycling and industrial-waste disposal regulations under local ordinances, etc.

<Useful Link>

Japan Traffic Management Technology Association http://204.227.185.48/en/index2.html Japanese Industrial Standards Committee (JISC) http://www.jisc.go.jp/eng/index.html Consumer Affairs Agency http://www.caa.go.jp/en/index.html Consumer Product Safety Association (CPSA) http://www.sg-mark.org/english/english20100810.pdf 3R Policies (Ministry of Economy, Trade and Industry) http://www.meti.go.jp/policy/recycle/main/english/index.html IPR Protection (Japan Customs) http://www.customs.go.jp/mizugiwa/chiteki/ipr_p.pdf

III - 2. Motorcycles

Customs classifications for motorcycles and sidecars (HS8711) are subdivided according to engine displacement.

<Sample HS classifications>:

Mopeds with engine displacement of 50 cc or less (8711.10), motor scooters with engine displacement of 50 - 250 cc (8711.20), and large motorcycles with engine displacement of more than 800 cc (8711.50)

In addition to the above customs classifications, motorcycles also are categorized based on the Road Transport Vehicle Act (which categorizes two-wheeled vehicles with engine displacement of 125 cc or less as motorized bicycles and permits only light two-wheeled vehicles with engine displacement of more than 125 cc and small two-wheeled motor vehicles to drive on expressways) and the Road Traffic Act (which categorizes those with engine displacement of 50 - 400 cc as standard motorcycles and those with engine displacement of 401 cc or more as large motorcycles).

Due to the wide range of laws and regulations, concerning import and sale, this section focuses on the Road Transport Vehicle Act.

1. Road Transport Vehicle Act

Standards are categorized as shown below, based on total engine displacement and vehicle size. Inspection, submittal of notification, and other procedures are required.

- (1) For motorcycles with total engine displacement of 126 250 cc, and up to 2.5m in length, 1.3m in width, and 2m in height, submittal of notification to the District Transport Bureau of the Ministry of Land, Infrastructure, Transport and Tourism and the prefectural land transportation bureau is required, subject to the condition that the vehicle satisfy the safety standards for a "Light two-wheeled motor vehicle". Type certification is sufficient for confirmation of safety standards, and official vehicle inspection is not needed.
- (2) For motorcycles with total engine displacement of 251 cc or more and larger than those described under paragraph (1) above, submittal of notification to the District Transport Bureau of the Ministry of Land, Infrastructure, Transport and Tourism is required, subject to the condition that the vehicle satisfy the safety standards for a "Small two-wheeled motor vehicle". Type certification is required for confirmation of safety standards, and official vehicle inspection is required as well.
- (3) Motorcycles with total engine displacement of 125 cc or less and smaller than those described under paragraph (1) above are categorized as "Motorized bicycles" and further subcategorized into type I (50 cc or less) and type II (51 125 cc), although the regulations applying to both subcategories are identical. Submittal of notification to the municipal government is required, subject to the condition that the vehicle satisfies safety standards. Type certification is sufficient for confirmation of safety standards, and official vehicle inspection is not needed.

There are three types of certification systems for imported vehicles in Japan: a. Formal designation system, b. New-vehicle notification system, and c. System for small quantities treatment. Each is summarized below.

a. Formal designation system:

Vehicle inspection is conducted by submitting a sample vehicle and documents in advance, and the system for ensuring uniformity among the vehicles is inspected as well. For two-wheeled motor vehicles that have undergone formal designation, during new inspection presenting an actual vehicle can be omitted. The formal designation system is used for imported vehicles planned for mass sale in Japan.

b. New-vehicle notification system:

Vehicle inspection is conducted by presenting a sample vehicle in advance. New inspection is conducted by merely confirming that the actual vehicle is the same as the sample vehicle, with systematic inspection of product uniformity omitted. This system is used to trucks and buses, which

have large numbers of specifications and vehicle types, also for small two-wheeled motor vehicles in some cases.

c. System for small quantities treatment

This system is applied only to imported vehicles planned for sale in small quantities in Japan (up to 2,000 units per year), presenting a sample vehicle is omitted and the documents submitted are simplified as well.

However, in inspection at the Transport Branch Office of the District Transport Bureau or the Office of motor-vehicle inspection and registration, while under the system described under paragraph (a) above there is no need to present the actual vehicle if an inspection certificate issued by the manufacturer or other party is available, under the systems described under paragraphs (b) and (c) above a license plate will not be issued until the actual vehicle has been checked to confirm that it matches the advance certification.

Furthermore, the above motor-vehicle certification systems do not apply to private importing, reimportation, or parallel importing. In these cases, conformity with safety standards needs to be confirmed through inspection of the individual vehicle. Since vehicles configured to overseas specifications differ on various points from Japanese specification vehicles, for example in headlight optical axes, meter displays, and exhaust measures, a variety of modifications are required to satisfy safety standards.

Application documents for a new vehicle inspection:

Certificate of conformity to safety standards / Certificate of completion of completed-vehicle inspection (for formal designation) / Certificate of completion of exhaust inspection (for formal permit and formal certification) / Certificate of transfer / Motor-vehicle customs clearance certificate / Parallel import motor-vehicle certificate (for parallel import) / Certificate of liability insurance / Certificate of payment of automobile weight tax / The user's certificate of residence, etc.

2. Act against Unjustifiable Premiums and Misleading Representations / Fair competition code

The motorcycle fair competition code of the Automobile Fair Trade Council, based on this act, establishes standards on representation in sale of new and used vehicles.

Other laws and regulations apply to motorcycles such as handling recalls and other measures of product liability as well as recycling.

Also, when importing a motorcycle for personal use in connection with moving to Japan from overseas, to be eligible for the special-purpose exemption there is a need to certify to the Customs office in charge of the import place that the motorcycle is intended for the personal use, that it already has been used by that person (for example by showing a vehicle registration certificate, insurance policy, or transfer certificate from the foreign country).

<Useful Link>

Import Clearance Procedures for Vehicles (Japan Customs)

http://www.customs.go.jp/english/c-answer_e/imtsukan/1109_e.htm

Motor Vehicle Inspection and Registration System in Japan (Ministry of Land, Infrastructure and Transport)

http://www.mlit.go.jp/english/inspect/index1e.html

Japanese Automobile Recycling Promotion Center (JARC)

http://www.jarc.or.jp/en/motorcycle/

III - 3. Helmets

Helmets (HS6506) are not only the purposes for use in vehicles. Due to the nature of the product, in cases such as accidents resulting from defects in helmets importers may be held liable for reparations.

1. Industrial Safety and Health Act

This act establishes standards for protective headgear (used to prevent risks from flying or falling objects or from falls) and prohibits use of the products that has not passed type certification by a registered type-testing agency. Its standards cover the following matters:

- Materials used in each component of protective headgear
- Designs of protective headgear
- Resistance performance of protective headgear to penetration
- Head dummies used in performance testing, conical strikers and jigs for use in testing
- Shock-absorption performance of protective headgear
- Labeling requirements of protective headgear

Since under this act helmets (protective headgear) are subject to type testing, when undergoing testing for the procedures are conducted by relevant documents such as a design of the protective headgear, an outline of manufacturing and testing equipment, other matters (for imported articles, documents on the overseas manufacturer's manufacturing and testing equipment are required) with samples to the application for testing and submitting it to the Technology Institution of Industrial Safety.

2. Consumer Product Safety Act

(1) PSC mark system (Product Safety of Consumer Products)

Helmets for motor vehicle users, which are designated as Specified products under a ministerial ordinance based on this act, a "Notice of Import of Specified products" needs to be submitted to the Regional Bureau of Economy, Trade and Industry with jurisdiction (or the Minister of Economy, Trade and Industry if the applicant's business facilities are in multiple districts) and compatibility testing by the designated testing agency (the Japan Vehicle Inspection Association) is required. The applicant may sell the product on which the labeling required, such as the PSC mark, has been affixed.

(2) SG mark system

The SG mark authorized by the Consumer Product Safety Association is a voluntary certification awarded to products recognized to satisfy the required standards for safe products established under the SG mark system. In case of an accident due to a defect in a product with the SG mark, liability insurance is provided up to a certain amount. The following helmets are eligible for the SG mark:

- Baseball helmets
- Helmets for baseball played with rubber balls and softball helmets
- Baseball and softball catcher's helmets
- Baseball pitcher's headgear
- Helmets for bicycles, electric powered wheelchairs, and moving playground equipment users
- Helmets for motor vehicle users

(3) System for report and publication of product accident information

In case of any serious product accident, importers of consumer products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of relevant products imported and sold, within 10 days from the day business operators including importers came to know the fact of the accident (Article 35). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents.

Compliance with the Product Liability Act (PL Act) also is required separately.

3. Other relevant laws

(1) Industrial Standardization Act (JIS standards) / Road Traffic Act

JIS standards include standards concerning protective helmets for motor vehicle users (JIST8133) and protective helmets for bicycle users (JIST8134).

While the Road Traffic Act does not restrict sale of protective helmets for motor vehicle users directly, the detailed regulations for enforcement of the Act establishes the standards on helmets (e.g., the weight up to 2kg).

(2) Household Goods Quality Labeling Act / Act against Unjustifiable Premiums and Misleading Representations

When selling subject products to ordinary consumers in Japan, labeling pursuant to the Household Goods Quality Labeling Act is required. Labeling must be affixed by the party with responsibility (e.g., an importer with a sales facility in Japan or the seller of the product) and the labeling must be clearly visible to and easily understandable to consumers and in the Japanese language.

Under the Act against Unjustifiable Premiums and Misleading Representations acts such as sale with excessive premiums and exaggerated or fraudulent labeling that could mislead consumers are prohibited.

(3) Customs Law (articles infringing on intellectual property rights), etc.

Import of articles infringing on intellectual property rights such as counterfeit character merchandise and use of misleading or unauthorized names (e.g., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights) is prohibited. Under the Unfair Competition Prevention Act and other laws, import will be suspended even if the importer is not aware that the goods are in violation of the law.

(4) Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law)

Import of helmets made of plastics or other materials using chemical substances categorized as Class I Specified Chemical Substances under this act is prohibited.

Caution is required concerning other regulations related to chemical substances as well.

<Useful Link>

Japan Advanced Information center of Safety and Health (JAISH)

http://www.jaish.gr.jp/eng/index.html

Consumer Affairs Agency

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

Consumer Product Safety Association (CPSA)

http://www.sg-mark.org/english/english20100810.pdf

Japanese Industrial Standards Committee (JISC)

http://www.jisc.go.jp/eng/index.html

IPR Protection (Japan Customs)

http://www.customs.go.jp/mizugiwa/chiteki/ipr_p.pdf

Chemical Management (Ministry of Economy, Trade and Industry)

http://www.meti.go.jp/english/policy/mono_info_service/kagaku/index.html

National Institute of Technology and Evaluation (NITE)

http://www.safe.nite.go.jp/english/index.html

III - 4. Passenger Vehicles

Due to the wide range of laws and regulations concerning import and sale of passenger vehicles, only the main laws and regulations are outlined below for reference.

1. Road Transport Vehicle Act

Actually driving a vehicle on public roads requires obtaining a vehicle license number after conducting domestic procedures such as official vehicle inspection and registration.

(1) When the importer is an agent:

There are three types of vehicle certification systems for prior inspection to ensure imported vehicles satisfy safety standards based on this act, grouped by type.

a. Formal designation system:

Vehicle inspection is conducted by submitting a sample vehicle and documents in advance, and the system for ensuring uniformity among the vehicles is inspected as well. For motor vehicles that have undergone formal designation, during new inspection presenting an actual vehicle can be omitted. The formal designation system is used for imported vehicles planned for mass sale in Japan.

b. New-vehicle notification system:

Vehicle inspection is conducted by presenting a sample vehicle in advance. New inspection is conducted by merely confirming that the actual vehicle is the same as the sample vehicle, with systematic inspection of product uniformity omitted. This system is used to trucks and buses, which have large numbers of specifications and vehicle types.

c. System for small quantities treatment

This system is applied only to imported vehicles planned for sale in small quantities in Japan (up to 2,000 units per year), presenting a sample vehicle is omitted and the documents submitted are simplified as well.

However, in inspection at the Transport Branch Office of the District Transport Bureau or the Office of motor-vehicle inspection and registration, while under the system described under paragraph (a) above there is no need to present the actual vehicle if an inspection certificate issued by the manufacturer or other party is available, under the systems described under paragraphs (b) and (c) above a license plate will not be issued until the actual vehicle has been checked to confirm that it matches the advance certification.

(2) Private importing and parallel importing:

Furthermore, the above motor-vehicle certification systems do not apply to private importing, reimportation, or parallel importing. In these cases, conformity with safety standards needs to be confirmed through receiving a vehicle customs clearance certificate during import customs clearance and then inspection of each individual vehicle as it leaves the bonded area. Since vehicles configured to overseas specifications differ on various points from Japanese specification vehicles, for example in headlight optical axes, meter displays, and exhaust measures, a variety of modifications are required to satisfy safety standards.

- a. Modifications to exhaust measures and other equipment to satisfy safety standards are conducted at a car maintenance workshop.
- b. Exhaust testing and other testing is conducted at an official agency authorized by the Ministry of Land, Infrastructure, Transport and Tourism.
- c. The vehicle is inspected at a land transportation bureau.

When importing for personal use in connection with moving to Japan from overseas, to be eligible for the special-purpose exemption there is a need to certify to the Customs office in charge of the place that the car is intended for the personal use, that it already has been used by that person (for example by showing a vehicle registration certificate, insurance policy, or transfer certificate from the foreign country).

2. Act on Recycling, etc. of End-of-Life Vehicles

Under this act, automakers or importers are required to take responsibility for recycling (appropriate processing and recycling, or disposal for CFCs) shredder dust, CFCs, airbags, etc. resulting when a vehicle they manufactured or imported reaches the end of its life, either themselves or through subcontracting.

Also, under the Act on the Promotion of Effective Utilization of Resources, motor vehicles are considered Specified Resources-Saved Products (products for which efforts to restrain generation of used articles, such as rationalization of use of raw materials and promoting long-term use, are required) and Specified Reuse-Promoted Products (products for which efforts to promote the utilization of recyclable resources or reusable parts are required). As such, importers and sellers of these products are required to carry out "three-R" (reduce, reuse, recycle) efforts.

3. Act on the Rational Use of Energy

In addition to the requirements for improvements to energy-conservation performance and labeling for energy efficiency, motor vehicles are subject to the "top-runner system" under which importers of vehicles at or above a certain quantity are required to conform at least to the energy efficiency of the best-performing product currently commercially available.

4. Other relevant laws

Under the Act against Unjustifiable Premiums and Misleading Representations, The Automobile Fair Trade Council has established the fair competition code regarding motor-vehicle labeling.

Other laws and regulations apply to motor vehicles such as recalls and other measures of product liability as well as the Automotive NOx and PM Law for some vehicles and JIS standards.

<Useful Link>

Import Clearance Procedures for Vehicles (Japan Customs)

http://www.customs.go.jp/english/c-answer_e/imtsukan/1109_e.htm

Motor Vehicle Inspection and Registration System in Japan (Ministry of Land, Infrastructure and Transport)

http://www.mlit.go.jp/english/inspect/index1e.html

3R Policies (Ministry of Economy, Trade and Industry)

http://www.meti.go.jp/policy/recycle/main/english/index.html

Japanese Automobile Recycling Promotion Center (JARC)

http://www.jarc.or.jp/en/recycling/

Act on Recycling, etc. of End-of-Life Vehicles

http://www.japaneselawtranslation.go.jp/law/detail/?id=127&vm=04&re=01&new=1

Act on the Rational Use of Energy

http://www.japaneselawtranslation.go.jp/law/detail/?id=1855&vm=04&re=01&new=1

III - 5. Yachts and Motorboats

Actual sailing of yachts or motorboats (HS8903) in Japan requires vessel inspection (including inspection for legally required equipments) and vessel registration. Sale of yachts and motorboats is regulated under the Ship Safety Act, the Act on Registration, etc. of Small-Sized Vessels, and the Ship Act.

1. Ship Safety Act

Under this act, technical standards on the structures and equipment of small vessels included among vessels for which national inspection (vessel inspection) is required are established in the Small-Vessel Safety Regulations and vessel inspection of craft with tonnage of less than 20 tons is conducted by the Japan Craft Inspection Organization (District Transport Bureaus and other organizations inspect large vessels with tonnage of more than 20 tons). Small crafts satisfying certain requirements, such as lengths of less than 3 meters and propulsion engines with maximum output of less than 1.5 kW or with no propulsion engines are exempted from vessel inspection.

Vessel inspection covers matters including manufacturing specifications and various specs, structural inspection using data of testing results and other documents, and durability testing of the vessel body and equipment. Since other tests including testing on the sea may be conducted as well, individual matters need to be checked in advance with the testing agency.

While in principle, vessel inspection is conducted for each body individually, preparations vary with the conditions of the vessel to be imported, for example in cases such as those of mass-produced outboard motors and legally required equipment for which the importer of other party has undergone formal approval (for legally required equipment such as life jackets, life rings, fire extinguisher, and nautical equipment, testing systems such as preparatory inspection at the manufacturing stage apply) and when documentation of testing results need to be checked by a classification society.

A Vessel Inspection Certificate, Vessel Inspection Handbook, and Vessel Inspection Stub are delivered to vessels that have passed vessel inspection. The Vessel Inspection Stub (showing the vessel inspection number, year of passing periodic inspection, number of the department awarding the stub, passing number and other information) must be affixed to both sides of the vessel in locations easily visible from outside.

2. Act on Registration, etc. of Small-Sized Vessels

Importers of small vessels (those with tonnage of less than 20 tons, not including fishing boats) must notify to the Minister of Land, Infrastructure, Transport and Tourism within 15 days from the importing date that the state of inscription of the vessel identification number on the vessel itself and the following matters prescribed by ministerial ordinance. Also the vessel must undergo measurement (Article 6 of the act) by the Japan Craft Inspection Organization and registration (the registers are operated by the Organization) before actual sailing. The information to be registered is shown below.

- (1) Type of vessel (steam or sail)
- (2) Port of registry (municipality where the vessel usually anchoring)
- (3) Length, width, depth (figures from measurement)
- (4) Tonnage
- (5) Vessel identification number (inscribed by the manufacturer or importer; under JIS standards, this number consists of 15 alphanumeric characters)
- (6) Type of propulsion engine (outboard motor, inboard motor, or inboard/outboard motor)
- (7) Name and address of owner (and shares if more than one owner)
- (8) Date of registration
- (9) Vessel number (assigned to each registered small vessel)

3. Ship Act

This act specifies that for vessels with tonnage of 20 tons or more, the owner must designate a port of registry, undergo measurement and registration by the District Transport Bureau with jurisdiction, and attain a country of registry (not required if the vessel will not be sailed). Through this process, a Vessel Country of Registry Certificate and a Vessel Registry Stub are issued.

4. Other relevant laws

(1) Act on Prevention of Marine Pollution and Maritime Disaster

Based on the MARPOL Convention (International Convention for the Prevention of Pollution From Ships), restrictions on emissions volume from diesel engines on vessels with output over 130 kW, as well as preparation of motor handling manual and approval by the Minister of Land, Infrastructure, Transport and Tourism, are required under this law.

(2) Industrial Standardization Act (JIS standards)

JIS standards relate to vessels, including standards concerning inscription of the vessel identification number as described in 2. Act on Registration, etc. of ... above, and those providing an outline of preparation of the motor handling manual for diesel engines based on 4. (1) Act on Prevention of Marine Pollution... above (JISF0406).

<Useful Link> Japan Customs http://www.customs.go.jp/english/index.htm Japan Craft Inspection Organization http://www.jci.go.jp/english/01.html Nippon Kaiji Kyokai (ClassNK) http://www.classnk.or.jp/hp/en/index.aspx Incorporation of ISO standards into Japanese Boat Safety Regulations (Ministry of Land, Infrastructure and Transport)

http://www.mlit.go.jp/english/2006/j_maritime_bureau/index.html

IV. Health and Beauty

IV - 1. Cosmetics

Cosmetics are regulated under the Pharmaceutical Affairs Law.

Checking HS classifications with the customs counselors offices is recommended. <Sample HS classifications>:

Beauty or make-up preparations and preparations for the care of the skin (HS3304)

The procedures mentioned below are not necessary for personal consumption and not intended for sale. However, on the whole such items must be in standard sizes of no more than 24 pieces per an item (ex. 24 lipstics regardless brand or color).

1. Pharmaceutical Affairs Law

When importing cosmetics for business purposes, (i) a "Manufacture Permit" is required. When purchasing imported products in Japan and then packaging, labeling, storing and selling them to market, (ii) a "Manufacture/Sale Permit" is required. When importing a product yourself and selling it in Japan, both permits (i) and (ii) are required. Also, the cosmetics to be imported must conform to the "Standards for Cosmetics" established by the Ministry of Health, Labour and Welfare (MHLW).

After obtaining the permits above, prior to import the following notices also must be submitted for each product: (iii) "Notice of Foreign Manufacturer / Seller of Cosmetics etc." (Pharmaceuticals and Medical Devices Agency), (iv) "Notice of Manufacture / Sale of Cosmetics" (the prefecture department in charge of pharmaceuticals), and (v) "Notice of Import of Cosmetics for Manufacture/Sale" (Kanto-Shinetsu or the Kinki Regional Bureau of Health and Welfare).

(1) Manufacture Permit, Manufacture/Sale Permit, and Approval of Manufacture/Sale (approval of each product)

First, (i) the Manufacture Permit Application is submitted to the prefecture department in charge of pharmaceuticals, and a permit is awarded for each manufacturing facility after inspection of the state of the manufacturer's structure and equipment, human-resources aptitude, and other conditions, to ensure that manufacture (or import) of the product would not present any health or hygiene problems. A general responsible technician with necessary qualifications such as those of a pharmacist must be appointed on a permanent basis.

(ii) The Manufacture/Sale Permit Application also is submitted to the prefecture department in charge of pharmaceuticals for the location of the business planning to sell the product (i.e., the facility at which the person with general responsibility for manufacture and sale are posted), together with the following documents: the copy of corporate registry, a doctor's medical certificate stating that the applicant does not have any mental disorder or similar condition, an organizational chart, documents certifying that the permanently posted persons with general responsibility for manufacture and sale have necessary qualifications such as those of a pharmacist, documents on systems for quality control and control of safety after manufacture and sale, and other documents. When both (i) a Manufacture Permit and (ii) a Manufacture/Sale Permit are held, the person with general responsibility for manufacture on the Manufacture/Sale Permit may be the same as the responsible technician on the Manufacture Permit, subject to the condition that his or hers is a permanent post. Inquire of each prefecture for details.

Next, approval of manufacture and sale of each product is based on comprehensive judgment following inspection of the cosmetic or other product to be imported; ingredients and quantities, manufacturing methods, dosage and administration, efficacy and effects, storage methods and expiration dates, its standards and testing methods, and other required information, either through the prefecture* or at the Pharmaceuticals and Medical Devices Agency, by submitting the required documents to that agency. However, if the product satisfies the Standards for Cosmetics established by the MHLW and all ingredients are labeled, this approval is not necessary.

* On applying for the approval through the prefecture, consult with the prefecture department in charge of pharmaceuticals on matters such as checking whether the product qualifies as a cosmetic or a quasi-drug.

(2) Notice of Foreign Manufacturer/Seller of Cosmetics etc.,

Notice of Manufacture/Sale of Cosmetics

Prior to import of the products by the Japanese manufacturer/seller (ii), a foreign manufacturer of cosmetics not requiring approval* must submit (iii) a Notice of Foreign Manufacturer/Seller of Cosmetics etc. (Form 115) to the Minister of Health, Labour and Welfare through the Pharmaceuticals and Medical Devices Agency and (iv) a Notice of Manufacture/Sale of Cosmetics (Form 39) to the prefectural governor. Notices (iii) and (iv) may be submitted to the prefecture department in charge of pharmaceuticals at the same time.

* Article 14 of the Pharmaceutical Affairs Law, Article 76 of the enforcement ordinance

(3) Notices of import

Furthermore, when importing for business purposes (v) a Notice of Import with the required items filled in, such as name and address of manufacturer/seller, type of permission, permit number, permit date of Manufacture/Sale Permit, and name of the product to be imported, must be submitted to the Kanto-Shinetsu Regional Bureau of Health and Welfare (East Japan) or the Kinki Regional Bureau of Health and Welfare (East Japan) or the Kinki Regional Bureau of Health and Welfare (West Japan excluding Okinawa. In Okinawa, the Narcotics Control Office.) for checking, by the time of customs clearance. After the checking, "the MHLW Checked Import Notice," will be returned with a confirmation mark, and importer should attach it to the import customs clearance documents and submit it to Customs.

If that within certain quantity ranges, import may be permitted in some cases for items such as product samples, items for personal use by doctors, and items for testing and clinical trials, through submittal of the required documents. However, quantities exceeding a certain amount require certification of pharmaceuticals inspection through conducting procedures with the pharmaceuticals department of the Regional Bureau of Health and Welfare.

Consulting with Customs or the Bureau of Health and Welfare in advance is recommended.

(4) Standards for Cosmetics and labeling requirements

Import and sale of products requires conformity with Standards for Cosmetics, which establishes rules concerning prohibited or restricted ingredients (the Negative List) and specific permitted ingredients (the Positive List).

The required items under the law, such as the name of the manufacturer/seller, product name, lot number or code, must be labeled directly on the container or package, and in principle all ingredients must be labeled. Other regulations include prohibition of fraudulent or misleading labeling.

2. Other relevant laws

(1) Act against Unjustifiable Premiums and Misleading Representations / Fair competition code

As for the products with fraudulent or incorrect labeling of country of origin, import is prohibited under the Customs Law and sale is prohibited under the Act against Unjustifiable Premiums and Misleading Representations. Sale with excessive premiums also is prohibited. As a voluntary industry standard based on this act, the Codes of Fair Competition regarding the representations of cosmetics, formulated by the Cosmetic Fair Trade Council Japan, apply to products considered cosmetics under the Pharmaceutical Affairs Law. These regulate matters such as labeling and advertising.

(2) Customs Law (articles infringing on intellectual property rights), etc.

Import of articles infringing on intellectual property rights such as counterfeit brand names (e.g., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights) is prohibited. Import will be suspended even if the importer is not aware that the goods are counterfeit.

(3) High Pressure Gas Safety Act

Regarding containers, import of spray and aerosol products requires a certificate showing that the products are exempt from application of this act. The product is approved exempt when the importer itself prepares the required documentation of testing results and it is confirmed that the products satisfies the requirements established in notificartion by the Minister of Economy, Trade and Industry (container no larger than 1 liter in capacity, with internal pressure no more than 0.8 megapascals).

If no such documentation is submitted or the results for any item are "fail," an inspection by the prefecture governor (import inspection application) is required.

Compliance with other laws and regulations, such as those recycling of containers and packaging, also is required.

<Useful Link>

Customs confirmation requirement concerning import restrictions in accordance with the Pharmaceutical Affairs Law (Japan Customs)

http://www.customs.go.jp/english/c-answer_e/imtsukan/1805_e.htm

Standards for Cosmetics (Ministry of Health, Labour and Welfare)

http://www.mhlw.go.jp/english/topics/cosmetics/index.html

Pharmaceuticals and Medical Devices Agency, Japan (PMDA)

http://www.pmda.go.jp/english/index.html

Outline of other relevant laws and ordinances referred to by Costoms (Japan Customs)

http://www.customs.go.jp/english/c-answer_e/imtsukan/1801_e.htm

Private importation of drugs, cosmetics, etc. (Japan Customs)

http://www.customs.go.jp/english/c-answer_e/imtsukan/1806_e.htm

Codes of Fair Competition regarding the representations of cosmetics (Cosmetic Fair Trade Council Japan)

http://www.cftc.jp/english/index.html

IV - 2. Aroma Products

Since there is not specific HS classification for aroma products, the HS code needs to be confirmed by checking with the customs counselors offices, based on detailed information of the actual product to be imported such as analysis of their ingredients. Use of the Advance Classification Ruling System is recommended.

This section covers only general notes on importing aroma products from that standpoint that aroma is not only intended for purposes of relaxation or healing but also sometimes included in the classification of pharmaceuticals or health products for beauty effects, etc.

So the "miscellaneous" goods such as oils, candles, and incense with no effect on the human body and enjoyed merely for their scents may be imported with no particular regulations.

1. Pharmaceutical Affairs Law

The key point is whether or not the specific product to be imported is subject to this law.

- Cosmetics: soap, lotion, perfumes, etc.
- Quasi-drugs: medicinal cosmetics, medicinal soaps, bath preparations (with effects such as treatment of eczema), etc.
- Medical devices: acupuncture and moxibustion implements, massage devices, magnetic therapy devices, etc.

While in general products applied directly to the skin can be considered subject to the law, check with the prefecture department in charge of pharmaceuticals.

Import and sale of products subject to the Pharmaceutical Affairs Law requires authorization such as a "Manufacture Permit" and a "Manufacture/Sale Permit" from the prefectural governor, and the importer must appoint on a permanent basis a person with general responsibility, such as a pharmacist, and have certain required equipment and structures at its business facility, among other requirements, for purposes such as quality checking and control of safety after sale.

Furthermore, depending on the product "Manufacture/Sale Approval" (acquired by applying to the Minister of Health, Labour and Welfare through Pharmaceuticals and Medical Devices Agency and undergoing the required inspection) may be required for each product. A "Notice of Manufacture/Sale" is required even if the product does not need approval.

For quasi-drugs and medical devices, application procedures for Foreign Manufacturer Certification are required, and for cosmetics a "Notice of Foreign Manufacture/Sale or Manufacturer" must be submitted to the Minister of Health, Labour and Welfare through Pharmaceuticals and Medical Devices Agency.

When import customs clearance, a "Notice of Import" also must be submitted after the Regional Bureau of Health and Welfare's checking.

2. Plant Protection Act

Products made from plants (ex. medicinal herbs) may be subject to quarantine, depending on their form and the degree of processing. In recent years, cases have been uncovered of illegal drugs such as stimulants and hallucinogens disguised as aroma products, so that monitoring of aroma products is increasing in strictness.

3. Consumer Product Safety Act

There are no particular import regulations on miscellaneous goods not subject to the Pharmaceutical Affairs Law (ex. oils, candles, and incense enjoyed merely for their scents). However, in case of any serious product accident, importers of the products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of products imported and sold, within 10 days from the day business operators (importer) came to know the fact of the accident (Article 35). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents.

Compliance with the Product Liability Act (such as civil indemnity) also is required separately.

4. Other relevant laws

(1) Act against Unjustifiable Premiums and Misleading Representations, etc.

With fraudulent labeling of country of origin or labeling that could mislead consumers are prohibited. In some cases of products subject to the Pharmaceutical Affairs Law, fair competition code and guidelines apply to them, as voluntary industry standards regulating matters such as labeling and advertising. Products imported as miscellaneous goods exempt from the Pharmaceutical Affairs Law may not be labeled as having medicinal effects. As for essential oils the voluntary certification system for conformity to labeling industry standards is established by the Aroma Environment Association of Japan.

(2) Customs Law (articles infringing on intellectual property rights)

Import of articles infringing on intellectual property rights such as counterfeit brand names (e.g., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights) is prohibited. Import will be suspended even if the importer is not aware that the goods are counterfeit.

Depending on the product, regulations may apply under other laws. Compliance with other laws and regulations, such as those concerning recycling of containers and packaging, also is required.

<Useful Link>

Japan Customs http://www.customs.go.jp/english/index.htm Advance Classification Ruling System (Japan Customs) http://www.customs.go.jp/english/c-answer_e/imtsukan/1202_e.htm Customs confirmation requirement concerning import restrictions in accordance with the Pharmaceutical Affairs Law (Japan Customs) http://www.customs.go.jp/english/c-answer_e/imtsukan/1805_e.htm Pharmaceuticals and Medical Devices Agency, Japan (PMDA) http://www.pmda.go.jp/english/index.html Consumer Affairs Agency http://www.caa.go.jp/en/index.html

IV - 3. Harbal and Natural Medicines

Since HS classifications vary with factors such as whether the product is a raw material or formulation for use in manufacture of pharmaceuticals and the sources of ingredients, checking with the customs counselors offices, based on details of the ingredients of the product information, is recommended. <Sample HS classifications>:

Materials of animal origin (HS0510), Materials of plant origin (1211), Organ therapeutic uses (3001), Mixtures of formulations not for retail sale (3003), and Mixtures of formulations for retail sale (3004)

However, these classifications include products not subject to the Pharmaceutical Affairs Law such as materials for perfumery use (which are included in HS 1211) and many products belonging to other classifications, such as plant extracts (2106), seeds and fruit for extraction of fixed oils (1201 - 1207), and citrus peels (0814), which can qualify as natural medicines depending on how they are used. Caution also is required concerning the fact that formulations may belong to HS 3303 - 3307 or 3808 case by case.

While in this section combinations of natural medicines are, on the whole, considered herbal medicines, this does not necessarily mean that all natural plant and animal materials primarily supplied to pharmacies are considered medicaments.

While the term medicaments in HS code 3003 or 3004 refers only to articles with therapeutic or preventive uses, the term pharmacy also includes products that do not necessarily have such uses (such as nutritional drinks). Also, classifications such as spices include some natural medicines as well (ex. red pepper, hydrangea, jasmine, etc.).

1. Pharmaceutical Affairs Law

Products belonging to the following categories are defined as pharmaceuticals under the law.

- (1) Those covered in the Japanese Pharmacopoeia
- (2) Those intended for use in diagnosis, treatment, or prevention of human or animal illness or injury, other than implements or machines (except quasi-drugs)
- (3) Those intended to affect the structure or functions of human or animal bodies, other than implements or machines (except quasi-drugs and cosmetics)

Products in category (1), those covered in the Japanese Pharmacopoeia, include many natural medicines.

Differentiation between pharmaceuticals and food is based on the "Judgment Criteria on the Scope of Pharmaceuticals" (Ministry of Health and Welfare Pharmaceuticals Bureau Director Notice No. 476). Since these criteria are revised frequently by the Ministry of Health, Labour and Welfare, the business operator must check for the latest information.

When importing for business purposes, (i) "Manufacture Permit" is required. When purchasing imported products in Japan and then packaging, labeling, storing and selling them to Japanese market, (ii) "Manufacture/Sale Permit" is required. When importing a product yourself and selling it in Japan, both permits (i) and (ii) are required.

After obtaining the permits above, if (iii) "Approval of Manufacture/Sale" is needed for each product then it must be obtained, and then the following notices also must be submitted for each product: (iv) "Notice of Foreign Manufacturer/Seller etc." (Pharmaceuticals and Medical Devices Agency), (v) "Notice of Manufacture/Sale of Pharmaceuticals" (the prefectural department in charge of pharmaceuticals where the Manufacture/Sale Permit was obtained), and (vi) "Notice of Import of Pharmaceuticals for Manufacture/Sale" (Kanto-Shinetsu or Kinki Regional Bureau of Health and Welfare).

When applying for (iii) Approval of Manufacture/Sale, a foreign manufacturer planning to export to Japan needs to receive (vii) "Foreign Manufacturer Certification". However, it also may appoint a business partner who has (ii) Manufacture/Sale Permit in Japan and apply for (iii) Approval to the Minister of Health, Labour and Welfare through the (ii) business pertner.

2. Industry standards

The Japan Kampo Medicines Manufacturers Association has established standards including the "Industry Standards on Residual Agricultural Chemicals" and the "GMP* for Kampo Products" to ensure the safety of herbal medicine. * GMP: <u>Good Manufacturing Practice</u>

3. Plant Protection Act / Act on Domestic Animal Infectious Diseases Control

Depending on the degree of processing as natural medicine or herbal medicine, products made from plants may require plant quarantine (in principle, all are subject to quarantine, and plants may not be imported with soil attached) and those made from animals may require animal quarantine (only for those designated for quarantine). In these cases, checking with the Plant Protection Station or the Animal Quarantine Service, based on details of the ingredients of the product information, is recommended. Either quarantine requires an inspection certificate issued by a government quarantine station of the exporting country or a certifiable agency.

4. Import Trade Control Order (CITES)

Under the Import Trade Control Order based on the Washington Convention (CITES), products made from endangered wild flora and fauna as well as their body parts and derivative products may be prohibited from import or their import may require documents depending on the type of products, such as an import license, a confirmation issued by the Ministry of Economy, Trade and Industry, or an export certificate or a certificate of origin issued by an agency of the government of the exporting country.

5. Narcotics and Psychotropics Control Act / Import Trade Control Order

If the imported products include poppy husk or other ingredients covered by this act, each business facility requires a license* from the Minister of Health, Labour and Welfare or the prefectural governor. Also obtaining a permit and other relevant procedures are required for each import.

Furthermore, since these products are subject to import approval under the Import Trade Control Order, they require application procedures for approval to the Ministry of Economy, Trade and Industry and confirmation with Customs during customs clearance.

* Article 3 (Licensing)

Minister of Health, Labour and Welfare:

Importer (qualification: Pharmaceutical Manufacture/Sale Permit), Pharmaceutical firm (qualification: Pharmaceuticals Manufacture/Sale Permit and Manufacture Permit), Manufacturer of exempt narcotic preparations (qualification: Manufacture Permit), Principal wholesaler (qualification: a business facility with a pharmacist and licensed as a pharmacy or seller), etc.

Prefectural Governor:

Wholesaler (same qualification with principal wholesaler), Pharmacy, Doctor, Pharmacist, etc. * Article 13 (Imports) - 16

Import by other than qualified narcotic importers is prohibited. Each import requires obtaining an import permit from the Minister of Health, Labour and Welfare. When imported, an export certificate issued by the exporting country must be submitted within 10 days from the date of import, and if not imported the import permit should be returned.

<Useful Link>

Outline of other relevant laws and ordinances referred by Customs (Japan Customs) http://www.customs.go.jp/english/c-answer_e/imtsukan/1801_e.htm Customs confirmation requirement concerning import restrictions in accordance with the Pharmaceutical Affairs Law (Japan Customs) http://www.customs.go.jp/english/c-answer_e/imtsukan/1805_e.htm Pharmaceuticals and Medical Devices Agency, Japan (PMDA) http://www.pmda.go.jp/english/index.html Food Safety Information (Ministry of Health, Labour and Welfare) http://www.mhlw.go.jp/english/topics/foodsafety/index.html Plant Protection Station http://www.pps.go.jp/english/index.html Animal Quarantine Service http://www.maff.go.jp/aqs/english/index.html CITES: Convention on International Trade in Endangered Species of Wild Fauna and Flora http://www.cites.org/ Consumer Affairs Agency http://www.caa.go.jp/en/index.html Importing or Bringing Medication into Japan for Personal Use (Ministry of Health, Labour and Welfare) http://www.mhlw.go.jp/english/topics/import/index.html

V. Hobbies

V - 1. Musical Instruments

As long as the product do not made from special materials (i.e., such as rosewood and ivory those regulated under the Convention on International Trade in Endangered Species of Wild Fauna and Flora: CITES, Washington Convention), no particular restrictions apply to musical instruments.

However, electronic musical instruments are subject to the regulations of the Electrical Appliance and Material Safety Law.

<Sample HS classifications>:

Pianos (HS9201), Guitars, Violins, and other string instruments (9202), Wind musical instruments (9205), Percussion instruments (9206), Electronic musical instruments (9207)

1. Electrical Appliance and Material Safety Law (Electronic musical instruments only)

All persons engaged manufacturing or importing electrical appliances in Japan shall notify the Ministry of Economy, Trade and Industry (Regional Bureau of Economy, Trade and Industry) of their business commencement within 30 days from the date of starting business (hereinafter referred to as a "Notifying Supplier"). The Notifying Suppliers have the obligation to secure the conformity of electric appliances and materials they import and sell to the mandatory technical standards.

The Order for Enforcement of this law groups subject products into the categories of "Specified Electrical Appliances and Materials" (115 items / Category A) and "Other Electrical Appliances and Materials" (339 items / Category B). Category A products must pass the third-party conformity assessment by an inspection agency registered with national government and receive a certificate of conformity. Self-confirmation of conformity is required for Categories A and B (all regulated Electrical Appliances and Materials) whose methods are designated by the government. Also this self-inspection may be subcontracted to a registered inspection bodies. The Notifying Supplier may sell the products only after they satisfy these standards, have been subjected to inspection and other tasks, and have been labeled with the marking required such as the PSE mark, the company name, rated current, etc.

The Notifying Supplier also is required to report any serious accidents after sale of the products.

Electronic musical instruments are classified as Category B. However, since wiring devices (such as power cables, plugs, and AC adapters) are classified as Category A, if the instrument includes such devices importers shall either undergo third-party conformity assessment for they import and obtain and keep the certificate thereof, or official copy of "the equivalent of certificate" through manufacturers of the specified electrical appliances concerned and keep the official copy of the equivalent of a certificate.

While so-called "vintage" electric musical instruments may be sold without the PSE mark, they require the application for special approval to the METI.

2. Import Trade Control Order (CITES)

Import of products made from wild flora and fauna regulated under the Washington Convention (CITES) is prohibited or requires import authorization such as an export certificate or a certificate of origin issued by an agency of the government of the exporting country and an import authorization issued by the Minister of Economy, Trade and Industry based on the categories of the appendices to the Convention. Since it is difficult to judge from general names whether an animal is subject to the Convention or has been raised as livestock, it is appropriate to show formal scientific names on the invoice.

3. Other relevant laws

(1) Act against Unjustifiable Premiums and Misleading Representations

The Keyboard Instrument Association of Japan established the fair competition code on representation of "Piano" and "Electronic-keyboard".

(2) Industrial Standardization Act (JIS standards)

There is the Musical Instrument Digital Interface (MIDI) standard (JISX6054).

(3) Customs Law (articles infringing on intellectual property rights), etc.

Import of articles infringing on intellectual property rights such as counterfeit branded products is prohibited. Note that import will be suspended even if the importer is not aware that the goods are counterfeit.

<Useful Link>

Electrical Appliance and Material Safety Law (Ministry of Economy, Trade and Industry) http://www.meti.go.jp/english/policy/economy/consumer/pse/index.html Japanese Industrial Standards Committee (JISC) http://www.jisc.go.jp/eng/index.html

V - 2. Mountaineering Equipment

1. Consumer Product Safety Act

(1) PSC mark system (Product Safety of Consumer Products)

When selling "mountaineering ropes", which are designated as Specified products under a ministerial ordinance based on this act, a "Notice of Import of Specified Products" needs to be submitted to the Director-General of the Regional Bureau of Economy, Trade and Industry with jurisdiction (or the Minister of Economy, Trade and Industry if the applicant's business facilities are in multiple districts) and compatibility testing by the designated testing agency (the Kita-Kanto Regional Office of the National Institute of Technology and Evaluation) is required. The applicant may sell the product on which the labeling is required by the act (the PSC mark).

(2) SG mark system

The SG mark authorized by the Consumer Product Safety Association is a voluntary certification awarded to products recognized to satisfy the required standards for safe products established under the SG mark system. In case of an accident due to a defect in a product with the SG mark, liability insurance is provided up to a certain amount.

The following mountaineering products are eligible for the SG mark:

- Karabiners
- Mountaineering helmets
- Camping tents
- Mountaineering ropes

However, the SG mark applies only to protective equipment used by mountaineers when climbing and descending cliffs or steep slopes. Special uses such as ranger training or rescue activities in the disaster are not eligible for the compensation system.

(3) System for report and publication of product accident information

In case of any serious product accident, importers of consumer products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of relevant products imported and sold, within 10 days from the day business operators including importers came to know the fact of the accident (Article 35). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents.

2. Other relevant laws

(1) Act for Controlling the Possession of Firearms or Swords and Other Such Weapons

A Sword Carry License is required for swords with blades 15cm or longer in length. Furthermore, it must be noted that possession of daggers with blades 5.5cm or longer in length is prohibited by the last amendment to the act.

(2) Industrial Standardization Act (JIS standards)

There are JIS standards concern some of products in this category, such as rope ladders (JISF3612), fiber ropes, and cooking stoves, etc.

<Useful Link>

Consumer Affairs Agency

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

Consumer Product Safety Association (CPSA)

http://www.sg-mark.org/english/english20100810.pdf

Customs' confirmation requirement concerning import restrictions in accordance with the Firearms and Swords Possession Control Law (Japan Customs)

http://www.customs.go.jp/english/c-answer_e/imtsukan/1808_e.htm

Japanese Industrial Standards Committee (JISC)

http://www.jisc.go.jp/eng/index.html

V - 3. Video Software

The product value of video software and musical works is extremely delicate, and the correct processing by businesses of rights such as copyright is an important prerequisite of importation. It must be noted that import of articles infringing on intellectual property rights (IPR), such as unauthorized copies, is a crime, and import will be suspended even if the importer is not aware that the goods are in violation of the law. The explanation in this section focuses on the customs procedures for authorization of suspected goods that they may infringe on IPR.

1. Customs Law (identification procedures)

(1) Identification procedures of suspected goods

When suspected goods have been discovered in customs examination of cargo declared for import or international mail (for which criminal investigation isn't conducted), identification procedures will begin, with the "Notice of Commencement of Identification Procedures" sent to the importer and the rights holder and, if the producer is clear from the customs clearance documents, the rights holder is notified of the name and address of the producer.

Within 10 business days from the date of this notice, the rights holder and the importer each submits to Customs their opinions and evidence concerning the suspected goods, Customs makes a determination on infringement of IPR, within one month.

Such cases also may be handled through voluntary transaction in which there is no dispute between the importer and the rights holder. Such transaction includes destruction, disposal, abandonment, and/or ship-back the cargo, obtaining a letter of consent to import, and modification of the cargo through means such as removal of infringement brand names or other parts. Cases such as obtaining a letter of consent to import and modification of the cargo through means such as removal of infringement brand names or other parts are identified as cases of noninfringement and the import is permitted, while in the other cases identification procedures are cancelled.

Both the rights holder and the importer are notified of the results of Customs identification procedures, and when identified as a case of noninfringement import is permitted. In cases identified as infringement, following a period for lodging an appeal (two months), the articles are seized and disposed by Customs if the importer has not carried out any voluntary transactions.

(2) Identification procedures under the system of appeal for import suspention

When cargo is discovered for which an application for import suspension has been accepted and identification procedures have begun, and, if the importer does not appeal for disputing the matter, the Customs director will makes a determination whether or not the suspected goods infringing IPR without the rights holder and the importer evidence and opinions (Article 62, Provision 16 of the Order for Enforcement the Customs Law).

After the Customs director makes determination on infringement of IPR, send an "Authorization Notice" to the rights holder and an "Authorization (or Seizure) Notice" to the importer. Following a period for lodging an appeal (two months), the articles are seized and disposed by Customs if the importer has not carried out any voluntary transactions.

If the importer appeal for disputing the matter, a "Notice of Deadline for Submittal of Evidence and Opinions" is sent to both the importer and the rights holder, and then the procedure described under (1) above follows subsequently.

2. Copyright Act

Even if those infringing on IPR somehow make it through customs procedure, under this act copyright and other rights are protected in Japan (and under the Universal Copyright Convention, the Berne Convention, the World Intellectual Property Organization [WIPO], etc.) for the period from creation until 50 years after the death of the creator (if the creator is a corporation or other organization, over the period of 50 years following release of the work, or 70 years for films). The consent of the copyright holder is required for use of such articles. For imports, the consent of the foreign copyright holder is required from the perspective of distribution rights as well.

Incidentally, under the Order of Enforcement of this act designated recording media (Blue-ray discs) are also subject to a system of compensation for private visual recording, and businesses (importers, sellers) must cooperate with the Society for Administration of Remuneration for Video Home Recording. Downloading illegally distributed software is prohibited for any purpose, including private purpose.

3. Industry labeling (Japan Video Software Association)

A measure for combating counterfeit copies of video software using hologram seals (pirate video detection marks) whose images cannot be copied easily is managed by Japan Video Software Association.

<Useful Link>

IPR Protection (Japan Customs)

http://www.customs.go.jp/mizugiwa/chiteki/ipr_p.pdf

System of an appeal for suspension of the importation of those goods infringing copyrights, etc. (Japan Customs)

http://www.customs.go.jp/english/c-answer_e/kinseihin/2003_e.htm

Appropriate Protection of Intellectual Property (Ministry of Economy, Trade and Industry)

http://www.meti.go.jp/english/policy/economy/chizai/index.html

VI. Other

VI-1. Wheelchairs

Wheelchairs for using by persons with disabilities or illness are grouped in HS8713.

1. Industrial Standardization Act (JIS standards)

There are JIS standards such as "manual wheelchairs" (JIST9201), "electric wheelchairs" (JIST9203), and "electric wheelchairs with steering wheels" (JIST9208). While these are voluntary standards, it is recommended that those wheelchairs conform to the standards, for which public expenses are provided under the "Services and Supports for Persons with Disabilities Act". As for the JIST9201, testing and assessment of conformity to is conducted by the Japan Bicycle Promotion Institute.

2. Road Traffic Act

Electric wheelchairs eligible to be considered "pedestrians" under the act are required to satisfy the following requirements based on the detailed regulations for enforcement of this act.

- (1) The size must not exceed 120 cm in length, 70 cm in width, and 109 cm in height.
- (2) The design of the wheelchair must have the following attributes:
 - (i) it must be electrically powered,
 - (ii) it must not exceed the maximum speed of 6km/h,
 - (iii) it must not have any sharp protuberances that could endanger pedestrians, and

(iv) it must be clearly distinguishable from motor vehicles and other vehicles by its exterior appearance.

The Japan Traffic Management Technology Association has established standards for electric wheelchairs and also certifies wheelchair models that are applied for. While these also are voluntary standards, since it has become de facto industry standard, it appears that in many cases electric scooters imported from Europe and North America which are capable of traveling at higher speeds are modified to keep speeds no higher than 6km/h when sold in Japan.

3. Consumer Product Safety Act

In case of any serious product accident, importers of consumer products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of relevant products imported and sold, within 10 days from the day business operators including importers came to know the fact of the accident (Article 35). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents.

The SG mark authorized by the Consumer Product Safety Association is a voluntary certification awarded to products recognized to meet the required standards for safe products established under the SG mark system. "Manually propelled wheelchairs" are eligible for the SG mark.

4. Electrical Appliance and Material Safety Law

Care is required for electric wheelchairs concerning whether or not they are regulated under this law. All persons engaged manufacturing or importing electrical appliances in Japan shall notify the Ministry of Economy, Trade and Industry (Regional Bureau of Economy, Trade and Industry) of their business commencement within 30 days from the date of starting business (hereinafter referred to as a "Notifying Supplier"). The Notifying Suppliers have the obligation to secure the conformity of electric appliances and materials they import and sell to the mandatory technical standards.

The enforcement regulations to this law groups subject products into the categories of "Specified Electrical Appliances and Materials" (115 items / Category A) and "Other Electrical Appliances and Materials" (339 items / Category B). Category A products must pass the third-party conformity assessment by an inspection agency registered with national government and receive a certificate of conformity. Self-confirmation of conformity is required for Categories A and B (all regulated Electrical Appliances and Materials) whose methods are designated by the government. Also this self-inspection may be subcontracted to a registered inspection bodies. The Notifying Supplier may sell the products

only after they satisfy these standards, have been subjected to inspection and other tasks, and have been labeled with the marking required such as the PSE mark, the company name, rated current, etc.

The Notifying Supplier also is required to report any serious accidents after sale of the products. While it depends on the product to be imported, electric wheelchairs may qualify as Category A (battery charges, transformers, electric vehicles, etc.) or as Category B (internal components, etc.). In either case, the PSE mark and designated labeling are required.

5. Act on Collection, etc. of Domestic Excises to be Imposed on Import Goods

Wheelchairs that qualify as implements for using by persons with disabilities (Article 14, provision 1, item 16 of the Customs Tariff Law) are exempt from consumption tax when imported and sold in Japan, as long as their models have been designated by the Minister of Health, Labour and Welfare. However, application of the exemption requires submittal to Customs of documents certifying that the imported product is designated by the Minister of Health, Labour and Welfare (ex., a copy of the official gazette for the date announcing the designation of exemption) and product pamphlets, etc.

<Useful Link>

Japanese Industrial Standards Committee (JISC) http://www.jisc.go.jp/eng/index.html Japan Traffic Management Technology Association http://204.227.185.48/en/index2.html Consumer Product Safety Association (CPSA) http://www.sg-mark.org/english/english20100810.pdf Electrical Appliance and Material Safety Law (Ministry of Economy, Trade and Industry) http://www.meti.go.jp/english/policy/economy/consumer/pse/index.html Application of the Consumption Tax on the Duty-Exemption Procedures (Japan Customs) http://www.customs.go.jp/english/c-answer_e/imtsukan/1703_e.htm Consumer Affairs Agency http://www.caa.go.jp/en/index.html

VI-2. Cribs

Though intended for baby use, these are classified as ordinary furniture for customs purposes, with those made from wood grouped in HS9403.50 (wooden bedroom furniture) and those made of metal in HS9403.20 (metal furniture, excluding office use).

Regulations apply to cribs under the Consumer Product Safety Act.

1. Consumer Product Safety Act

(1) PSC mark system (Product Safety of Consumer Products)

Cribs are specified as "Special specified products" under a ministerial ordinance based on this act. Importers of cribs must submit a "Notice of Import of Specified Products" to the Regional Bureau of Economy, Trade and Industry with jurisdiction (or the Minister of Economy, Trade and Industry if the applicant's business facilities are in multiple districts), and compatibility testing by the designated testing agency (the Japan Recreation And Miscellaneous Goods Safety Laboratory) is required.

The applicant may sell the product only after it complies with the standards and the labeling required such as the PSC mark indicating that inspection and other tasks have been conducted has been affixed.

(2) SG mark system

The SG mark authorized by the Consumer Product Safety Association is a voluntary certification awarded to products recognized to meet the required standards for safe products established under the SG mark system. In case of an accident due to a defect in a product with the SG mark, liability insurance is provided up to a certain amount. Cribs also are eligible for the SG mark.

Cribs eligible for the PSC mark and the SG mark are those designed mainly as beds for sleeping and childcare of infants under 24 months in age (excluding rocking cribs).

(3) System for report and publication of product accident information

In case of any serious product accident, importers of consumer products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of relevant products imported and sold, within 10 days from the day business operators including importers came to know the fact of the accident (Article 35, provisions 1 and 2 of the Act, and Article 3 of the Ordinance for Enforcement of the Act). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents.

Compliance with the Product Liability Act (PL Act) also is required separately.

2. Other relevant laws

(1) Household Goods Quality Labeling Act

Textile Goods Quality Labeling Regulations under this act require labeling showing the composition of fibers, care labeling such as home washing etc., name of labeler and contact address and other information. Textile products using natural or artificial leather parts also are subject to Miscellaneous Manufactured Goods Quality Labeling Regulations which require labeling kind of material.

(2) Act on Control of Household Products Containing Harmful Substances

It is prohibited to sale articles not meeting the standard values established for designated chemical substances used in textiles, such as insect repellents (e.g., dieldrin), which could be harmful to human health. For products for infant use in particular, regulations stipulate that formalin (resin treatment) must not be present in detectable amounts.

(3) Industrial Standardization Act (JIS standards)

There is JIS standard on wooden baby beds (JISS1103).

(4) Customs Law (articles infringing on intellectual property rights, mislabeling), etc.

It is prohibited to import articles infringing on intellectual property rights such as counterfeit character merchandise (e.g., goods infringing on trademark rights, copyright, neighboring rights, patent rights, utility model rights, or design rights). Under the Unfair Competition Prevention Act and other laws, import will be suspended even if the importer is not aware that the goods are in violation of the law.

Also, under the Act against Unjustifiable Premiums and Misleading Representations acts such as sale with excessive premiums and exaggerated or fraudulent labeling that could mislead consumers are prohibited.

<Useful Link>

Japan Recreation and Miscellaneous Goods Safety Laboratory (MGSL) http://www.mgsl.or.jp/English/Eindex.htm Consumer Product Safety Association (CPSA) http://www.sg-mark.org/english/english20100810.pdf Consumer Affairs Agency http://www.caa.go.jp/en/index.html Japanese Industrial Standards Committee (JISC) http://www.jisc.go.jp/eng/index.html

VII. Outline of Relevant Laws

VII - 1. Act against Unjustifiable Premiums and Misleading Representations

This act is intended to protect interests of general consumers by (i) ensuring fair competition through prohibiting provision of excessive premiums and (ii) prohibiting exaggerated or fraudulent advertising or other representations by businesses to induce customers. Put another way, this act is intended to ensure fair competition between businesses and protect consumers' ability to choose products and services appropriately by restricting misleading representations and excessive premiums.

The competent authority of this act was changed from the Japan Fair Trade Commission to the Consumer Affairs Agency in 2009.

This section provides an overview of area (ii) above, labeling restrictions, in particular, since it is related to import and sale of products from overseas.

1. Overview of restrictions on misleading representations

Since the information shown when they buy products (including not just information shown on the products such as packaging and labeling but also various advertising and sales methods) is an important source of information for decision-making when consumers choose products, labeling that could mislead consumers about product quality, "Much Better" misleading labeling^{*1}, is prohibited.

Furthermore, misleading or possibly misleading information on matters other than quality, such as price, "Much More Favorable" misleading labeling^{*2}, also is prohibited. In response to such violations, orders will be issued to take corrective measures "Warnings" or "Cautions", depending on degree, and orders will be issued to take steps such as elimination of the act in violation and corrective advertising.

In addition to the Consumer Affairs Agency, prefectural governors and police departments are authorized under this act as well.

*¹ "Much Better" misleading labeling

- i.e.: The representations causing consumers to think products/services are much better than the actual ones or much better than those of other entrepreneurs contrary to the fact.
- ex.: labeling a product consisting of 80% cashmere as "100% cashmere"

*² "Much More Favorable" misleading representations

- i.e.: The representations causing consumers to think products/services are much more favorable than the actual ones or much better than those of other entrepreneurs contrary to the fact.
- ex.: labeling a product as containing "twice as much as the competition" when in fact it contains roughly the same amount as the competition

2. Labeling causing consumers to think products are excellent

This refers to advertising activities such as those misstating product quality as better than it actually is or implying that a product is much better than competing products when in fact it is not. It must be noted that under this act importers are responsible not just for deliberate mislabeling but also for mislabeling of products even if they are unaware of such mislabeling.

For the purpose of determining whether or not representations constitutes labeling causing consumers to think products are excellent, the Consumer Affairs Agency may require the businesses to submit, within 15days, documentation providing reasonable evidence to back up the representations (restrictions on unproven advertising claims: Article 4, provision 2). The key point is that the businesses (importer) are responsible for the proving themselves.

3. Misleading representations of country of origin

Especially designated as involving the possibility of misleading general consumers is representations concerning country of origin (a country in which a treatment or process effecting substantial change to the substance of the goods made). In response to the social problem for the disguising of the origins of food products in recent years, in May 2009 the JAS Law was revised to establishing severe penalties for the violations. In many cases, representations is regulated under other relevant laws such as the Food Sanitation Act, the Household Goods Quality Labeling Act and, as necessary, detailed regulations such as fair competition code for individual products or industries.

Under the Act against Unjustifiable Premiums and Misleading Representations, the examples below are considered misleading representations.

Ex.: Apparel products sewed in China of Japanese material may not be labeled "Made in Japan" (such products may be labeled "Made in China of Japan fabric").

Labeling that could cause consumers to imagine a product was produced in a country other than its country of origin (country or region names, flags, or crests) is prohibited, etc.

4. Advertising on the Internet

In recent years, e-trading targeted at consumers using the Internet (B to C) has been increasing rapidly. In light of the nature of Internet transactions, in which the steps from advertising through the purchase contract can be completed easily, it is thought that such transaction has higher risks of troubles, and as such an even higher level of strictness in advertising is required.

5. Fair competition code

While this act primarily covers matters such as prohibitions common to all industries, fair competition codes are autonomous rules established by industry associations such as fair trade conferences in each industry to regulate matters such as required labeling standards, and prohibitions, in light of product characteristics and other relevant Japanese laws and regulations, and operated with the approval of the Consumer Affairs Agency (former times, the Japan Fair Trade Commission).

While businesses should participate in and comply with these codes on their own initiative, some fair trade conferences have established fair-business-practice marks that serve to gain the trust of consumers.

<Useful Link>

Act against Unjustifiable Premium and Misleading Representations (Amendment: 2005) http://www.japaneselawtranslation.go.jp/law/detail/?id=49&vm=04&re=01&new=1

VII - 2. Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging / Act on the Promotion of Effective Utilization of Resources

The Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging is the act to promote reduction and recycling of container and packaging wastes. This act is under cojurisdiction of five ministries (the Ministry of the Environment, the Ministry of Economy, Trade and Industry, the Ministry of Finance, the Ministry of Health, Labour and Welfare, and the Ministry of Agriculture, Forestry and Fisheries). The duties of labeling and of collection and recycling, which deeply concern import and sale of products from overseas, are inextricably related to this act and the Act on the Promotion of Effective Utilization of Resources. This section provides the overview including these matters.

1. Subjects of the labeling requirement

The containers and packaging materials subject to this act, consisting of metal, glass, paper, and plastic, are listed below. Regulations on labeling for identification of materials are established under the Act on the Promotion of Effective Utilization of Resources. The main subject of them is products designated for labeling (i.e., products requiring labeling for promoting sorted collection of wastes).

- (1) Aluminum cans, Steel cans
- (2) Glass bottles* (colorless, amber, other colors)
- (3) Paper drink packs, paperboard containers, paper containers and packaging*
- (4) PET bottles* (soft drinks, alcoholic beverages, soy sauce, processed soy-sauce products (noodle soup. etc.), sweet sake-like (*mirin*) seasonings, vinegar, seasoning vinegar, dressing-type seasoning (non-oil), milk beverage, etc.), plastic containers and packaging*
- In addition, under the Act on the Promotion of Effective Utilization of Resources include the following:
- (5) Small-sized secondary batteries (small-sized seal lead batteries, nickel-cadmium batteries, nickel metal-hydride batteries, lithium secondary batteries)
- (6) Construction made of Vinyl chloride materials (tube, gutters, window frame, floor and wall), etc.

Materials denoted with an asterisk (*) above must be recycled by businesses. Containers and packaging made of multiple materials such as paper packs with plastic caps also are subject to labeling requirements showing percentages of materials.

However, Small-scale businesses are exempt from the Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging. Such businesses refer to those satisfying the following requirements on both net sales and number of employees.

- (1) Manufacturing: net sales of no more than 240 million yen and no more than 20 employees
- (2) Commercial, service: net sales of no more than 70 million yen and no more than five employees Under the Act on the Promotion of Effective Utilization of Resources the requirement of labeling to

identify materials applies to businesses ordering production of containers and packaging as well.

2. Exceptions to the labeling requirement

Since containers and packaging refers originally to articles that will be separated from their content products and no longer used once the content products have been consumed, the following are not considered containers and packaging.

- Those for which the contents are not products: direct-mail envelopes, containers and packaging used in the home, etc.
- Those for services instead of products: cleaning bags, video rental bags, etc.
- Those that would still be used after separation from the contents: CD cases, cases for musical instrument and camera, etc.

Materials identification marks are intended for sorted disposal of containers and packages that manufacturers, user businesses (including importers) are required to recycle under the Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging. It would be problematic to labeling materials identification marks voluntarily on containers and packaging not subject to the recycling requirement under the act. While the subjects of materials identification marks under the Act on the Promotion of Effective Utilization of Resources basically are the same as those of the recycling requirement under the Act on the Promotion of Sorted Collection and Recycling are the same as those of the recycling requirement under the Act on the Promotion of Sorted Collection and Recycling of Containers and

Packaging, there are exceptions, such as the fact that under the former small-scale businesses, which are exempt under the latter, are required to label materials identification and cases in which labeling is not required despite the requirement of recycling. For example,

- While the recycling requirement applies to glass containers, they are exempt from the requirement to label materials identification
- Containers and packaging for industrial use are exempt from the labeling requirement and also the recycling requirement
- Nonwoven fabric, cellophane which is not grouped in the plastic category, etc.

3. Labeling requirements for imported products

When indicating container and packaging materials and composition and trademark use, importers and sellers must use the same materials identification marks as used for domestic Japanese products. Put another way, when importing and selling completed products (nothing changed) from a foreign manufacturer, the trading company importing the products is not required to label the materials identification marks if it makes no instruction concerning matters such as the form of the product and the container and packaging are not labeled in Japanese. However, acutually such a case would involve issues whether products with no Japanese-language labeling would be accepted by Japanese consumers and the coherence of labeling requirements under other relevant Japanese laws and regulations such as Food Sanitation Act, Act on Standardization and Proper Labeling of Agricultural and Forest Products (JAS Law), Pharmaceutical Affairs Law, Household Goods Quality Labeling Act, and Measurement Law, etc. For this reason, the subject of the labeler responsible under this act will vary depending on whether the importer or retailer affixes Japanese-language labeling. When affixing a Japanese-language label, the requirement may be fulfilled together with other component materials identification labels on the container and packaging surface.

4. Subjects of the recycling requirement

The following businesses other than small-scale businesses (not subject to the recycling requirement) are subject to the recycling requirement calculated in accordance with the amount of containers and packaging they generate.

- Users of designated containers: businesses using containers for the products they sell
- Manufacturers of designated containers: businesses manufacturing those containers
- Users of designated containers and packaging: businesses importing and selling products with those containers and packaging

These designated businesses may choose to fulfill their recycling requirement by (i) collecting used products themselves (e.g., returnable bottles of beer and soft drinks), (ii) subcontracting collection to the designated body (the Japan Containers and Packaging Recycling Association), or (iii) using their own independent route under the approval of the competent minister. However, since sorted collection of waste rules vary by municipality, in many cases businesses fulfill this requirement using method (ii), paying the charges for subcontracting of recycling.

As an agent for the recycling requirement on designated businesses, the Japan Containers And Packaging Recycling Association collects container and packaging waste from municipal storage facilities and subcontracts recycling processing to recycling businesses chosen through a bidding process. Violators of the recycling duty (i.e., free-rider businesses, who fail to satisfy the recycling requirement despite the fact that they are subject to it as designated businesses) will be subject to warning, announcement, and the order of improvement from the competent minister, and will be fined if they do not comply with the order.

<Useful Link>

Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging (Amendment: 2006) http://www.japaneselawtranslation.go.jp/law/detail/?id=88&vm=04&re=01&new=1

Act on the promotion of Effective Utilization of Resources

http://www.japaneselawtranslation.go.jp/law/detail/?id=80&vm=04&re=01&new=1

3R Policies (Ministry of Economy, Trade and Industry)

http://www.meti.go.jp/policy/recycle/main/english/index.html

The Japan Containers and Packaging Recycling Association

http://www.jcpra.or.jp/eng/index.html

VII - 3. Industrial Standardization Act (JIS Mark Labeling System)

The Japanese Industrial Standards (JIS) based on the Industrial Standardization Act is the national standards that are intended to promote efforts such as ensuring appropriate quality of mining and manufacturing products, providing product information, technology advancement, increasing productivity, improving the competitive environment, and ensuring interchangeability and compatibility of interfaces. JIS are enacted by the competent ministers (the Minister of Economy, Trade and Industry, the Minister of Land, Infrastructure, Transport and Tourism, the Minister of Health, Labour and Welfare, the Minister of Agriculture, Forestry and Fisheries, the Minister of Education, Culture, Sports, Science and Technology, the Minister for Internal Affairs and Communications, and the Minister of the Environment) through investigating and deliberating by the Japanese Industrial Standards Committee (JISC).

1. JIS mark Labeling System

- JIS standards are classified into three categories by the nature of contents:
- "Basic standards" (those establishing matters such as terminology, codes, units, etc.)
- "Methods standards" (those establishing methods such as those of testing, analysis, inspection, measurement, etc.)
- "Products standards" (those establishing matters such as product shapes, dimensions, materials, quality, performance, functions, etc.)

In most cases, labeling of the JIS mark system under which such labeling is approved after the product has received certification by an Accredited Certification Body that it conforms to certain quality and other requirements prescribed in these product standards.

The JIS mark comes in three designs for "Mining and manufacturing products", "Process technologies" and "Particular aspects" such as products that concern to the environment or to the elderly and people with disabilities.

2. Japan Accreditation System for Product Certification Bodies of JIS Mark (JASC)

When a manufacturer, importer, or seller of mining and manufacturing products desires to affix the JIS mark on the product, it must undergo certification by a third-party agency registered with the national government (Accredited Certification Body). The JIS mark may not be used based solely on self declaration of conformity with the standards. The national government accredits Accredited Certification Bodies under the international standard ISO/IEC Guideline 65 (in Japan, JISQ0065: General requirements for bodies operating product certification systems). Furthermore, under ISO/IEC Guide 28 (JISQ1001: General guidance on a third-party certification guidelines and sectoral guidelines on certification. In this way, the system for assessment of conformity to standards is consistent on an international basis. In addition to inspecting quality management systems (including inspection equipment, inspection methods, and appointment of persons responsible for quality control), Accredited Certification Bodies take responsibility for testing sampled products.

A competent minister is designated for each JIS standard, and Accredited Certification Bodies are subject to periodic renewal of registration (every four years), maintenance and administration through on-site inspections and other tasks, and, as necessary, administrative sanction such as orders on conformity and improvement. While the national government can take same measures as necessary for certified manufacturers, cancellation of certification is conducted by the Accredited Certification Body that certified the product.

3. The Japan National Laboratory Accreditation system (JNLA)

Under ISO/IEC17025 (in Japan, JISQ17025: General requirements for the competence of testing and calibration laboratories), the National Institute of Technology and Evaluation (NITE) issues registration certificates to businesses registered for the testing capabilities within the scope of application on factors such as organization, quality systems, records management, personnel, facility conditions, and traceability of measurement, to ensure the ability to provide appropriate test results.

Note that in addition to the JNLA system there are other testing-facility accreditation systems as well.

As well as the EN standards in Europe and the ANSI standards in the United States, basically JIS standards are voluntary standards, and it is not compulsory certification. However, in some cases the standards are cited in enforceable laws and regulations, in response to the movement toward international standardization (under the ISO and IEC, etc.), as exemplified by the WTO Agreement on Technical Barriers to Trade (WTO-TBT). For example, JIS standards are inextricably linked to standards based on laws and regulations such as the Building Standards Act (restrictions on formaldehyde in building materials), the Fire Service Act (technical standards on fire-fighting equipment), the Electrical Appliance and Material Safety Law, the High Pressure Gas Safety Act, and other laws and regulations.

In addition, many standards, such as those on quality management (ISO9000 = JISQ9000), environmental management (ISO14000 = JISQ14000), and information security management (ISO/IEC27001 = JISQ27001), while not compulsory, are subject to aggressive promotion of their adoption by businesses and organizations.

<Useful Link>

Industrial Standardization Act (Amendment: 2005) http://www.japaneselawtranslation.go.jp/law/detail/?id=20&vm=04&re=01 Japanese Industrial Standards Committee (JISC) http://www.jisc.go.jp/eng/index.html National Institute of Technology and Evaluation (NITE) http://www.iajapan.nite.go.jp/jnla/en/index.html

VII - 4. Household Goods Quality Labeling Act

This act aims to make the labeling of household goods relating to their quality fair and appropriate so that the interests of general consumers can be protected. (Article 1)

1. Household goods designated for labeling

While the list of products designated for labeling is reviewed as necessary in light of factors such as change in lifestyles and needs, such products are grouped into four categories under Quality Labeling Regulations. Designated products are subject to the labeling standards, which consist of "labeling matters," the quality to be indicated such as components, performance, usage, storage condition, etc., and "compliance matters," rules for labeling.

- a. Textile goods: 35 items (1) Yarn (2) Woven fabrics, knitted fabrics, and lace (3) Jackets (4) Trousers or pants (5) Skirts (6) Dresses (7) Pullovers, cardigans, and other sweaters (8) Dress shirts, open-necked shirts, polo shirts, other shirts (9) Blouses (10) Aprons, cooking aprons, business and work wear (11) Overcoats, topcoats, raincoats, other coats (12) Rompers and children's overalls (13) Underwear (14) Nightwear (15) Socks (16) Tabi (Japanese-style socks to be worn with kimono) (17) Gloves (18) Handkerchiefs (19) Blankets (20) Sheets (21) Towels and *tenugui* (Japanese-style hand towels) (22) Haori (short coat to be worn over kimono) and kimono (traditional Japanese clothes) (23) Mufflers, scarves, and shawls (24) Dressing gowns (25) Curtains (26) Carpets (limited to those with piles) (27) Coverlets (limited to those made of towels) (28) Futon (Japanese-style guilts or mattresses) (29) Blanket covers, futon covers, pillow covers and bedspreads (30) Table cloths (31) Neckties (32) Swimming wear (33) Furoshiki (Japanese-style wrapping cloths) (34) *Obi* (Japanese-style sash belts for kimono) (35) Obijime (sash fasteners) and Haori strings b. Plastic manufactured goods: 8 items (1) Washbasins, tubs, buckets and bathroom utensils (2) Baskets (3) Trays (4) Water bottles (5) Tableware and kitchen utensils (6) Polyethylene or polypropylene bags (7) Hot water bottles (8) Portable toilet pots and toilet utensils (excluding fixed type) c. Electrical appliances: 17 items (1) Electric washing machines (2) Electric rice cookers (3) Electrically heated blankets (4) Electrical vacuum cleaners (5) Electrical refrigerators (6) Ventilation fans (7) Air conditioners (8) Television receivers (9) Electric juicers, mixers, and juicer-mixers (10) Electric panel heaters (12) Electric roasters (11) Electric pots (13) Electric shavers (14) Microwave ovens (15) Fluorescent desk lamp stands (16) Electric griddles (17) Electric coffee makers d. Miscellaneous manufactured goods: 30 items (1) Thermos bottles (2) Bags (3) Umbrellas (4) Synthetic detergents, soap for laundry or kitchen use and detergents for household or furniture use (5) Household or furniture wax (6) Urethane foam mattresses and spring mattresses (7) Shoes (8) Gloves that are wholly or partly made of leather or synthetic leather (9) Desks and tables (10) Chairs, stools and zaisu (legless chairs used in a tatami room) (12) Synthetic rubber cutting boards (11) *Tansu* (chests of drawers) (13) Jackets, trousers, skirts, dresses, coats, and pullovers, cardigans and other sweaters made wholly of or partly using leather or synthetic leather
 - (14) Paints (15) Tissue paper and toilet paper

(16) Tableware and kitchen utensils painted with Japanese lacquer or cashew nut resin coating

(17) Adhesives (18) Tableware and kitchen utensils made of tempered glass

(19) Tableware and kitchen utensils made from borosilicate glass or glass ceramics (22) Toothbrushes

(20) Shopping carts (21) Sunglasses

(23) Aluminum foil for serving food or kitchen use (24) Baby feeding bottles

(26) Kettles (25) Pots and pans (27) shoji (Japanese sliding doors) paper

(28) Bleaching agents for clothes, kitchen or household use

(29) Polishing agents for kitchen, household or furniture use (30) Water purifiers

In principle, products combining or made of one or more of the above products require labeling based on the Quality Labeling Regulations for each relevant function or item.

2. Compliance measures

The Prime Minister or the Minister of Economy, Trade and Industry may instruct the manufacturer or distributors or labeling agents to provide labeling in accordance with the act, in the case that they are not provided or a product is not labeled in accordance with the labeling standards.

If a manufacturer, etc. does not follow such instructions, the Minister may announce publicly the name of the manufacturer, etc. to that effect. (Article 4)

If improvements are not seen after this instruction and announcement process, the Minister may order to compel appropriate labeling under threat of penalty (Article 5) and, furthermore, may order to refrain from the sale of the goods without proper labeling (Article 6).

To enforce this act, the Minister may conduct onsite inspections or collect reports from manufacturers, etc. The authority for such onsite inspections, etc. has been delegated to the Regional Bureaus of Economy, Trade and Industry or to individual prefectures (Article 19).

3. Labeling of imported products

In the particulars to be displayed, the name (full name or trade name) and contact address (address or phone number) must be indicated in a conspicuous location, readily visible to the consumer in the Japanese language.

Labeling of country of origin shall comply with the relevant standards (Fair Trade Commission Notice no. 34, 1973) based on the Act against Unjustifiable Premiums and Misleading Representations.

While this act does not cover products for industrial use, caution is required concerning products that might be sold directly to consumers at home superstores or other outlets. Similarly, while products not offered for sale are exempt from the law, if they include product that might be sold to consumers labeling is required.

<Useful Link>

Household Goods Quality Labeling Act (Amendment: 1999)

http://www.japaneselawtranslation.go.jp/law/detail/?id=1874&vm=04&re=01

Quality Labelling Laws of Household easily understood brochure (Ministry of Economy, Trade and Industry / As of March 2009)

http://www.meti.go.jp/policy/consumer/seian/hinpyo/pamphlet/pamphlet 03.html

VII - 5. Act on Control of Household Products Containing Harmful Substances

For the perspective of safety control of household products, products not conforming to the standard values of designated chemical substances that could be harmful to the human body are prohibited from sale (Article 5).

Businesses are responsible for selling products on the market only after confirming that they do not violate the applicable standards. After products are brought to market, they are monitored by prefecture governments and other regulators and, if necessary, orders will be issued to take corrective measures such as recall and improving quality control (Article 6).

Substance	Subject	Standard
Hydrogen chloride	Household detergent fluids	Acid content no more than 10% by
Hydrochloric acid	(not including toxic formulas	amount and container of designated
	including the substances at left)	strength
Vinyl Chloride	Household aerosol products	None detected using infrared absorption
		spectrum
4, 6-Dichloro-7 (2, 4,	The following textile products:	30 ppm or lower (30 μ g or lower per gram
5-trichloro phenoxy)	Diaper covers, underwear,	of sample) using gas chromatography
-2-Trifluoro methyl	sleepwear, gloves, socks and	with electron-capture detector
benz imidazole (DTTB)	stockings, innerwear, outerwear,	
	headwear, bedding, pillows and	
	mats, household yarn	
Sodium hydroxide	Household detergent fluids	Alkali content no more than 5% by
Potassium hydroxide	(not including toxic formulas	amount and container of designated
	including the substances at left)	strength
Tetrachloroethylene	Household aerosol products	0.1% or lower using gas chromatography
	Household detergent	with electron-capture detector
Trichloroethylene	Household aerosol products	0.1% or lower using gas chromatography
	Household detergent	with electron-capture detector
Tris (1-aziridinyl)	The following textile products:	None detected using gas
phosphine oxide (APO)	Sleepwear, bedding, curtains,	chromatography with flame-photometric
	pillows and mats	detector
Triphenyl tin compound	The following textile products:	None detected using flameless atomic
Tributyl tin compound	Diapers, diaper covers, bibs,	absorption spectrometry and thin layer
	underwear, sanitary bands, sanitary	chromatography
	underpants, gloves, socks and	
	stockings	
	Household adhesives, household	
	paints, household waxes, shoe	
	polish, shoe cream	
Bis (2, 3-dibrom propyl)	The following textile products:	None detected using gas
phosphate compound	Sleepwear, bedding, curtains,	chromatography with flame-photometric
(TDBPP)	pillows and mats	detector

Subject household products, their standards are established for each category of restricted substance.

Substance	Subject	Standard	
Formaldehyde	 (1) The following textile products: Diapers, diaper covers, bibs, underwear, sleepwear, gloves, socks and stockings, innerwear, outerwear, headwear, and bedding for infants under 24 months in age 	 (1) Absorbance difference under acetylacetone method of 0.05 or lower, or 16 ppm or lower (16 μg or lower per gram of sample) 	
	 (2) The following textile products: Underwear, sleepwear, gloves, socks and stockings, <i>tabi</i> Wigs, false eyelashes, false mustaches and beards, adhesives used to keep socks and stockings in place 	(2) 75 ppm or lower (75 μg or lower per gram of sample) under acetylacetone method	
Methanol (methyl alcohol)	Household aerosol products	5w/w% or lower using gas chromatography with hydrogen flame detector	
Organic mercury compounds	The following textile products: Diapers, diaper covers, bibs, underwear, sanitary bands, sanitary underpants, gloves, socks and stockings Household adhesives, household paints, household waxes, shoe polish, shoe cream	None detected using flameless atomic absorption spectrometry (background value must not exceed 1 ppm)	
Di-benzo (a, h) anthracene Benzo (a) anthracene Benzo (a) pyrene	 Household wood preservatives and wood pesticides containing creosote oil Household wood preservatives and wood pesticides processed using creosote oil and compounds thereof 	 10 ppm or lower using gas-chromatography mass spectrometer (10 μg or lower per gram of sample) 3 ppm or lower using gas-chromatography mass spectrometer (3 μg or lower per gram of sample) 	

However, this act does not apply when stricter safety measures are clearly required under the standards or other stipulations of other laws or regulations (Article 2).

- (1) Products subject to regulation under the Food Sanitation Act
- Food products, additives, apparatus, containers and packaging, toys, detergents, and similar products (2) Products subject to regulation under the Pharmaceutical Affairs Law
- Pharmaceuticals, quasi-drugs, cosmetics, medical devices, and similar products
- (3) Products subject to legal regulation (standards) of manufacture, import, or sale under other government ordinances

Although this act applies to products for household use and not those for industrial use, it must be noted that products such as "adhesives" that could be used both in industry or businesses and in households are, for the most part, considered household products, unless it is clear from the purpose of the product and the manner in which is sold that it is for industrial use only.

<Useful Link>

Act on Control of Household Products Containing Harmful Substances (Act No.112 of 1973) http://www.nihs.go.jp/mhlw/chemical/katei/PDF/100415houritu_eiyaku.pdf

VII - 6. Electrical Appliances and Material Safety Act

All persons engaged manufacturing or importing electrical appliances in Japan shall notify the Ministry of Economy, Trade and Industry (Regional Bureau of Economy, Trade and Industry) of their business commencement within 30 days from the date of starting business (hereinafter referred to as a "Notifying Supplier"). The Notifying Suppliers have the obligation to secure the conformity of electric appliances and materials they import and sell to the mandatory technical standards.

The order for enforcement of this act groups subject products into the categories of "Specified Electrical Appliances and Materials" (115 items / Category A) and "Other Electrical Appliances and Materials" (339 items / Category B). Category A products must pass the third-party conformity assessment by Registered Conformity Assessment Bodies, which is registered by national government, and receive a certificate of conformity. Self-confirmation of conformity is required for Categories A and B (all regulated Electrical Appliances and Materials) whose methods are designated by the government. Also this self-inspection may be subcontracted to designated inspection bodies.

The Notifying Supplier may sell the products only after they satisfy these standards, have been subjected to inspection and other tasks, and have been labeled with the marking required such as the PSE mark, the company name, and rated current.

The Notifying Supplier also is required to report any serious accidents after sale of the products.

1. Outline of procedures

The following procedures are legal obligations that must be performed.

(1) Confirmation of the name of the electric product

Under this act there are 454 items (115 items of Category A and 339 items of Category B) of electrical appliances and materials, correct interpretation is needed concerning whether the product is subject to the act, based on its operating principles and the name of the product. For example, for an electric product that operates only with an AC adapter, basically the AC adapter (Category A) is subject while the main unit is not subject.

(2) Confirmation of details of activities

Legal obligations differ among activities such as manufacture, import, and sale. For example, when modifying a product after importing it, both an importer notice and a manufacturer notice are required, and the business will bear other obligations such as conforming to technical standards as well.

(3) Notification of business commencement

Businesses manufacturing or importing electric products must notify the Regional Bureau of Economy, Trade and Industry having jurisdiction of the necessary information (address, name, starting date of business, type category of the relevant electric product, and other information) within 30 days from the date of starting business. Regulations also require other notices, such as item change notices, notices of succession of business, and cessation notices, etc.

(4) Compliance with Technical Requirements

The Notifying Supplier (manufacturer or importer) must ensure the electric product conforms to the established technical standards. There are two types of technical standards: Japanese standards and conformity standards established by the International Electrotechnical Commission (IEC; standards). The business must confirm conformity to one or the other of these standards.

(5)-1 Third-Party Conformity Assessment

If the electric product is categorized as a "Specified Electrical Appliances and Materials / Category A", it cannot be sold unless it has undergone conformity testing by a Registered Conformity Assessment Body and received a certificate of conformity. If the notifying importer does not have its own testing equipment, it must retain a certificate equivalent to the certificate of conformity, specifically a copy (an issued official copy, not a photocopy made by the foreign manufacturer) of a certificate issued to the foreign manufacturer by a Registered Conformity Assessment Body.

(5)-2 Self-confirmation of conformity

Testing methods are established by ministerial ordinance, and testing records must be kept for three years. If the Notifying Supplier does not have its own testing equipment, it may subcontract the Self-confirmation of conformity to an outside testing firm. However, the Notifying Supplier remains responsible for performance of the legal obligations, and it must be able to present the testing records and explain the state of confirmation of conformity with technical standards in case of the on-site inspection by the national government or the National Institute of Technology and Evaluation.

(6) Marking Requirements

The Notifying Supplier may sell the electrical appliances and materials only after it has been attached in accordance with the act such as the PSE mark^{*}, the company name, and rated current, to show that it conforms to the technical standards and that this conformity has been certified through required testing, and the seller is obligated to confirm these matters. Only the Notifying Supplier may carry out such labeling under the act, and the Notifying Supplier may not use such labeling without performing the above obligations.

* PSE: Product Safety Electrical Appliance & Materials

2. Compliance measures after sale of the product

As necessary, the Minister of Economy, Trade and Industry may require reports from each business (Article 45), conduct on-site inspections (Article 46), issue improvement orders in case of the violation has been confirmed (Article 11), prohibit labeling, which effectively means prohibit sale (Article 12), order recalls, and order to take other necessary measures to prevent the spread of the hazards or damages (Article 42-5).

<Useful Link>

Introduction for Importers Based in Japan (Ministry of Economy, Trade and Industry) http://www.meti.go.jp/english/policy/economy/consumer/pse/index.html Electrical Appliances and Material Safety Act (Amendment: 2005) http://www.japaneselawtranslation.go.jp/law/detail/?id=1916&vm=04&re=01&new=1

VII - 7. Consumer Product Safety Act

This act has been containing four important systems.

1. PSC mark system (Product Safety of Consumer Products)

Manufacturers and importers of products specified as "Specified products" under a ministerial ordinance based on this act must submit the "Notice of Manufacture/Import of Specified Products" to the Regional Bureau of Economy, Trade and Industry with jurisdiction (or the Minister of Economy, Trade and Industry if the applicant's business facilities are in multiple districts).

Specified products must conform to the technical requirements established by a Ministerial Ordinance for each product (Self-confirmation of conformity), and sale of products without the safety mark showing compliance with these standards (the PSC mark) is prohibited.

Furthermore, Products specified as "Special specified products" (#) (3 products) must undergo the comformity testing by a third-party assessment body (Testing agencies are listed below).

	Specified products	Notes	Testing agency
	Mountaineering rope	Limited to ones for body securing	Kita-Kanto Regional Office, National Institute of Technology and Evaluation
	Pressure cookers and autoclaves for home use	Limited to ones with inner capacity of 10 liters or less and designed to use with gauge pressure of 9.8 kilopascals or more	Japan Recreation And Miscellaneous Goods Safety Laboratory Japan Electrical Safety & Environment Technology Laboratories
	Helmets for motor vehicle users	Limited to ones for two-wheeled motor vehicles and bicycles with motors	Japan Vehicle Inspection Association
	Oil water heaters	Limited to ones with kerosene consumption of 70 kw or less and heat exchanger capacity of 50 liters or less	Japan Heating Appliances Inspection Association
	Oil bath boilers	Limited to ones with kerosene consumption of 39 kw or less	Japan Heating Appliances Inspection Association
	Oil heaters	Limited to ones with kerosene consumption of 12 kw or less (7 kw or less for natural ventilation type with the open-type combustion stoves)	Japan Heating Appliances Inspection Association
#	Crib	Limited to ones designed for a baby less than 24 months, home use for sleeping or childcare, with a swing type being excluded	Japan Recreation And Miscellaneous Goods Safety Laboratory
#	Portable laser-applied equipment	Limited to ones designed for displaying text or patterns by irradiating laser light (limited to visible rays)	Japan Quality Assurance Organization UL Japan Cosmos Corporation
#	Hot-water circulators for bathtubs	Limited to ones designed mainly for home with an inlet and spout combined, equipped with a water circulation device for warming water with a maximum amount of water circulation being less than 10 liters.	Japan Electrical Safety & Environment Technology Laboratories Japan Gas Appliances Inspection Association UL Japan Japan Heating Appliances Inspection Association Cosmos Corporation

Subject products ("#" indicates "Special specified products")

2. System for Report and Publication of Product Accident Information

In case of any serious product accident, importers of consumer products are required to submit a report to the Prime Minister on the name and model of the product, the details of the accident, and the quantity of relevant products imported and sold, within 10 days from the day business operators including importers came to know the fact of the accident (Article 35). All importers of consumer products in Japan, regardless of their size or type of business, are required to submit this report on accidents. Compliance with the Product Liability Act also is required separately.

3. The Long-term Use Consumer Product Safety System

(1) The Long-term Use Consumer Product Safety Inspection System (Specified Maintenance Products)

Under this system, manufacturers and importers of products subject to "Specified Maintenance Products" must submit the "Notice of Manufacture/Import of Specified Maintenance Products" to the Regional Bureau of Economy, Trade and Industry with jurisdiction.

In addition, such products must be explained for required information such as a "Standard Period of Use" which is established as a guideline for safe use, time for an inspection, contact information, etc.

Specified Maintenance Products (7 items):

Hot water heater (Petroleum), Bathtub water heating unit (Petroleum), FF hot air-expelling heater (Petroleum), Built-in dishwasher (Electric), Bathroom dryer (Electric), Kitchen water heating unit Indoor installation (City gas / LP gas), Bathtub water heating unit Indoor installation (City gas / LP gas)

(2) The Long-term Use Consumer Product Safety Indication System

Under the Electrical Appliance and Material Safety Law, manufacturers and importers are required to submit notices to the Regional Bureau of Economy, Trade and Industry. However, by this act, some electric devices specified products with a large number of accident reports due to deterioration over time are now required to bear warning labels regarding deterioration and "Standard Period of Use".

* Coverd products (5 items):

Fans, Air-conditioners, Ventilatiors, CRT televisions, Washing machines (Automatic type / Double-drum type),

4. SG mark system

The SG (Safety Goods) mark authorized by the Consumer Product Safety Association is a voluntary certification awarded to products recognized to confirm the required standards for safe products established under the SG mark system. A total of 115 products (as of April 2010), including the "Specified products" (*) described in **1.** above, are designated eligible for SG mark.

(1) Products for babies and infants (19 items)

Carry cots, Cribs*, Playpens, Baby carriages, Belts for carrying infants, Infant pipe carriers, Baby walkers, Racks for infants and children, Infant chairs, Infant high chairs, Table attached type infant chairs, Protective fences for infants, Tricycles for preschool children, Foot-operated toy cars, Swings, Swings for one infant, Playground slides, Horizontal bars for preschool children, Telescoping poles for Japanese *Koinobori* (carp-shaped streamers)

(2) Goods for the aged (9 items)

Sticks, Manual wheelchairs, Rollators for disabled persons (rollators and walking tables), 4-wheel walking aids, Electrically operated beds in home use, Chairs and seats with electrical mechanisms to assist standing up and sitting down, Bath/shower chairs, Portable toilets, Portable toilet seats for aged

(3) Furniture, household and kitchen utensils (19 items)

Plastic covers for bathtub, Warm-water circulators for bath*, Spring mattresses for household use, Hot water bottle for warming (*Yutanpo*), Mailboxes, Toilet paper holders, Shopping carts, Aluminum alloy ladders for household use, Metal stepladders for household use, Aluminum alloy articulated ladders for household use, Adhesive hooks, Kitchen cabinets, Children's chests, Two-level beds, Storage cabinets for kitchen (with cooking range table), Portable clotheshorse (*Monohoshi*), Tension shelves and rods, Rotary hangers, Legless chairs for tatami rooms(*Zaisu*)

(4) Kitchen utensils (7 items)

Household electrical pressure pots and pressure cookers*, Metal pans, Aluminum saucepans, Cookware for electric hooves, Cooking oil filter utensils, Ice crushers for household, Can openers

(5) Sporting and leisure goods (35 items)

Metal bats, Fiber-reinforced plastic bats, Baseball helmets, Helmets for rubber ball baseball and softball, Catcher helmets for baseball and softball, Headgear for baseball pitcher, Breast protectors for baseball and softball, Roller-skates, Inline skates, Skate boards, Kick skaters, Beach parasols, Underwater mask(Diving goggles), Badminton rackets, Golf practice nets, Golf club shafts, Golf clubs, Outdoor handball goals, Mobile soccer goals, Mats for physical training, Vaulting boxes for physical training, Spring boards for vaulting boxes, Volleyball equipment, Mobile basketball equipment, Shock absorbing pads for physical training, Karabiners, Climber's helmets, Mountaineering ropes*, Camping tents, Trekking-poles, Helmets for snow leisure, Headgear for snow leisure, Bamboo swords for Kendo(*Shinai*), Kendo equipments and gear, Table-tennis tables

(6) Fitness equipment for home-use (8 items)

Treadmills for household, Bicycle ergometers for household, Steppers, Rowing machines, Skipping rope, Chest exercisers, Gymnastic chinning equipments, Muscle training equipments

(7) Equipment for gardening (4 items)

Manual lawn mowers, Pole pruners, Portable kerosene burners for outdoor use, Garden hand sprayers for household

(8) Equipment for bicycle (4 items)

Bicycles, Helmets for users of bicycle, electromotive wheelchair etc, and running play gear; Child seats for bicycle, Air pumps for bicycle

(9) Others (10 items)

Protective helmets for motor vehicle users*, Portable automotive jacks, Hydraulic garage jacks for automobils, Automotive windshield washer liquid, Shopping carts, Pocket gas lighters, Cotton swabs, Children's umbrellas, Glass bottles for carbonated beverage, Portable laser pointers*

In case of an accident due to a defect in a product with the SG mark, liability insurance is provided up to a certain amount.

To labeling the SG mark, a business needs to have the product certified by the Consumer Product Safety Association in advance. There are two testing methods available: (i) Registration of plants and other facilities and type confirmation, and (ii) Lot certification.

Under method (i), the company is inspected to ensure that it has the ability to produce products in conformity with standards on a continual basis, model testing (type confirmation) is conducted for products produced at a plant that has passed inspection, and if this inspection is passed products passing in-house inspection may be labeled SG mark within the permissive period (which varies by product).

Under method (ii) Lot certification, the testing agency certified by the Consumer Product Safety Association tests samples of lots, and only lots that pass this sample testing may be labeled SG mark. Certification standards include those on external appearances, structure, dimensions, strength, stability, and other physical performance needed for safety, materials, and, for some products, chemical and biological performance. Subjects that should be indicated on the product and its manual are prescribed on each product basis.

<Useful Link>

Outline of the Consumer Products Safety Act (Ministry of Economy, Trade and Industry) http://www.meti.go.jp/policy/consumer/seian/shouan/contents/outline_psc_act090331e.pdf Consumer Affairs Agency

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

Consumer's Safety and the SG Mark System (Consumer Product Safety Association) http://www.sg-mark.org/english/english20100810.pdf

The Long-term Use Consumer Product Safety System (Ministry of Economy, Trade and Industry) http://www.meti.go.jp/english/policy/economy/consumer/pro_safe_info.pdf

Consumer Product Safety Act (Amendment: 2007)

http://www.japaneselawtranslation.go.jp/law/detail/?id=1838&vm=04&re=01&new=1

Caution on use of this document, escape clauses/disclaimer

JETRO shall not be held liable for any direct, indirect, derivative, special, attendant, or punitive damages or loss of income arising in connection with the content of this document, whether due to contracts, unlawful action, negligence, or any other cause. This applies even if JETRO is made aware of the possibility of such loss.

While this document has been prepared based on information considered reliable, no guarantee is made concerning its accuracy or completeness. JETRO may have issued or issue in the future documents that are not in agreement with the main points of this document.

Title : Handbook for Consumer Products Import Regulations 2010

Date of publication : October 2010

Publisher : Japan External Trade Organization (JETRO)

Unauthorized copying or reproduction is prohibited.