



# **Guide to Safety Assurance for Products Imported to Japan**

## Introduction

It is essential to remember that importers are responsible for the safety of the products they handle.

The Basic Consumer Act specifies that business operators are responsible for ensuring the safety of the products they supply, and for providing necessary consumer information in a clear and easy-to-understand manner. This means that importers are required to comply with laws and regulations, confirm product safety, provide information on the quality and safety of products through appropriate labeling, and take prompt measures for problems.

MIPRO provides information on laws, regulations, and procedures for import and sales through seminars and the publications. This new guidebook highlights safety and summarizes points for importers to remember about products that are often handled in the small-lot import business.

It is our hope that this guidebook will help everyone involved in the import business to consider the safety of imported products.

**November 2013**

**Manufactured Imports and Investment Promotion Organization (MIPRO)**

### [Notes]

- This guidebook is an English translation of a revised version of the Guide to Safety Assurance for Products Imported to Japan (in Japanese only) published in March 2012.
- Regulations described in this guidebook are mainly related to product safety. The content in this guidebook does not cover all regulations regarding the products described herein. For more detailed information on related regulations, please see other reference materials published by MIPRO and websites of the relevant government ministries and agencies.
- Content described in this guidebook is valid as of September 2013. Please continue to check for further revisions.

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# 1. For the Safety of Import Goods

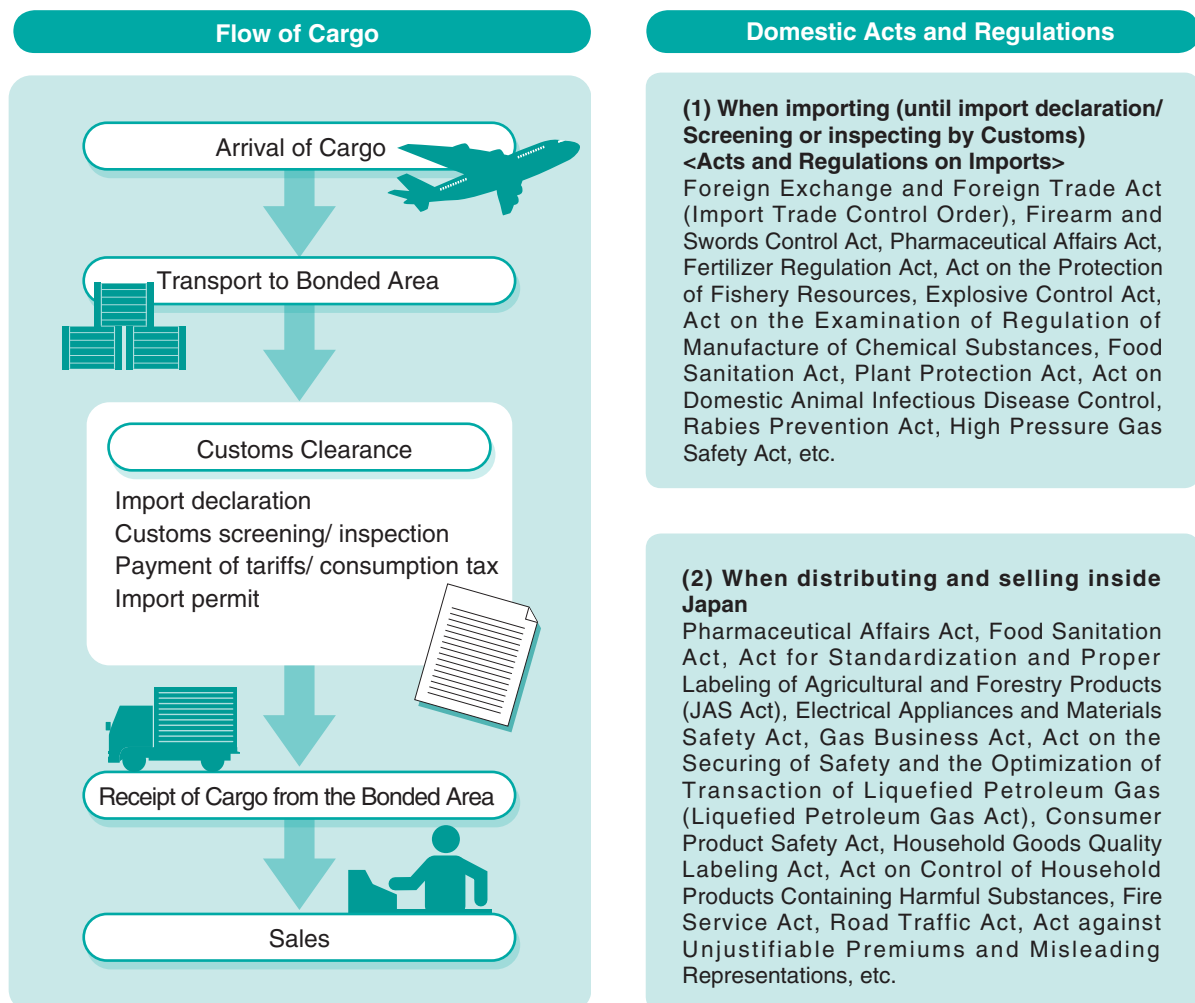
## Import Goods and Japanese Acts and Regulations

Products imported into and sold in Japan are subject to regulation. First of all, let's take a look at the relationship between import goods and domestic acts and regulations.

Some import regulations are designed to achieve major regulatory purposes such as the protection of domestic industry, the assurance of product quality and safety, and the protection of the natural and social environment. These regulations are categorized as Import Acts and Regulations and stipulate the inspection and screening of imports by Customs authorities during clearing procedures for the required permission or approval (**see (1) below**).

Other regulations control the sale or use of import goods rather than the actual import of said goods. Such regulations apply to products without regard to whether they are imported or manufactured domestically. These regulations hold importers responsible for the products they import just as domestic manufacturers are held responsible for the products they manufacture. The major content of such regulations relates to applications and permission to import and sell, inspections, compliance with specifications and standards, and the labeling of import goods (**see (2) below**).



Importers are required to comply with regulations for import products and assure the safety of the products they import.



(Some act names are abbreviated.)

## JIS and JAS

Japanese Industrial Standards (JIS) and Japan Agricultural Standards (JAS) were established as national standards. These standards are voluntary and applied as appropriate according to the intention of business operators.

JIS	JIS	JIS were established as national standards based on the Industrial Standardization Act, whose purpose is to promote industrial standardization. When applying JIS as reference values for technical standards specified by domestic acts and regulations, JIS are enforced.	
	JIS labeling system	The JIS labeling system allows business operators who are approved by an accredited certification body to use the JIS label on products approved by said certification body.	
JAS	JAS	JAS were established as national standards based on the Act for Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Act) whose purpose is to improve the quality of agricultural and forest products. Targets are food and forestry products.	 (Certified Organization)
	JAS qualification system	The JAS qualification system allows business operators to use the JAS label on products satisfying JAS standards.	

## Voluntary Industrial Standards and Qualification Systems

Each industry also places effort into ensuring the quality and safety of products and winning the confidence of the consumer public by establishing voluntary standards and qualification systems. Individual standards and qualification systems allow products that meet their standards to be labeled to show consumers that the quality and safety of the products have been confirmed. For example, the SG mark is for consumer products, the ST mark is for toys, the SF mark is for toy fireworks, and the S mark is for electric products.

In addition, regardless of the application of voluntary industrial standards or qualification systems, it is important for importers to have a system for the voluntary examination of the capability, strength and endurance of products (or the outsourcing of testing and attachment of the test results) to assure safety.

### Private Imports

Imports for private use are relatively free of import acts and regulations based on the assumption that responsibility for product safety is borne by the private importer.

This limits the importer to private use, prohibits sale or distribution to a third person, including free distribution to the general public, regardless of whether the importer is an individual or a company. The number of products that can be imported is also limited to the amount appropriate for private use.

Items on the embargo list such as illegal drugs, firearms, explosives, and counterfeit currency are prohibited even for private importers, and quarantine is also required to prevent the import of harmful animals, plants, and diseases.

## Product Safety Measures to be Taken by Importers

The safety of imported goods is monitored and guided by the government based on safety regulations specified by domestic acts and regulations according to the items imported, such as the Food Sanitation Act for food products and Pharmaceutical Affairs Act for cosmetics. Importers are required to take safety measures appropriate to the individual regulations and the characteristics of the item or items imported.

### ■ Voluntary Principles for Product Safety (Guidelines for the Establishment of Voluntary Principles on Product Safety)

To ensure the safety of imported consumer products\*, the Ministry of Economy, Trade and Industry (METI) established Voluntary Principles for Product Safety, which specifies that importers ensure product safety centering on the items listed below.

**\*Note:** Consumer products are defined as those used by general consumers for daily life, except those for which safety measures are covered separately by other acts and regulations, including the Food Sanitation Act and Pharmaceutical Affairs Act.

#### Voluntary Principles for Importers

- (1) Importers should not merely seek high-performance or low-cost products, but they should also recognize their social responsibility to provide safe products to consumers and establish a safe and secure society by placing a priority on consumers and product safety assurance in the basic policies of their business, and disseminate the specific policies to employees.
- (2) A department responsible for the handling of product safety should be installed in the company and given the authority to give directions to other departments in a cross-sectoral manner.
- (3) In the case that any department obtains information on a product accident, said department should immediately report such to top management.
- (4) Any information on a product-related accident should be disclosed immediately and appropriately to concerned individuals outside the company, such as distributors and those involved in installation and repair.
- (5) Even when the seriousness of a product-related accident does not require a report to the government, it still must be reported to the National Institute of Technology and Evaluation (NITE).
- (6) In the case that there is risk of insufficient funds for emergencies such as a product recall, a system must be established to secure funding for the purchase of insurance, etc.

\*There are other items that major companies are responsible for.

### ■ Product Liability

The Product Liability Act (PL Act) specifies that the manufacturer, etc. shall be liable for damages arising from the infringement of life, body or property of others which is caused by the defect in the delivered product which was manufactured, processed, imported, or provided with the representation of name, etc. In the case of imported goods, importers bear the same responsibility as manufacturers.

In order to improve and ensure safety, importers are expected to place a priority on manufacturing process management, pre-shipment inspections, provide proper labeling, manuals, and aftercare to prevent the occurrence or expansion of damage after the sale of imported goods.

In order to promote compliance with the PL Act, the PL Insurance System is available to small and medium-sized enterprises through each local Chamber of Commerce and Industry. Sole proprietors are eligible to join the insurance system after becoming members of the local Chamber of Commerce and Industry.

## Response to Product-Related Accidents

### ■ Requirement to report serious product-related accidents to the Consumer Affairs Agency

The Consumer Product Safety Act specifies that any person engaging in the manufacture or import of consumer products who comes to know that a serious product-related accident has originated with the consumer products manufactured or imported thereby shall report such to the Consumer Affairs Agency within 10 days from the day on which said person comes to know the fact (System for the reporting and publication of product-related accident information).

The range of product-related accidents includes death, serious injury or sickness (requiring 30 or more days for treatment), residual disability, carbon monoxide intoxication, and fire (confirmed by the fire department). Unless it is shown that any such accident was not caused by a product-related defect, it will be deemed a product-related accident. In other words, even when improper use of a product by the consumer causes the accident, if factors exist that may have led to improper use (for example, a lack of caution marks, etc.), the accident is deemed a product-related accident and must be reported.

Information contained in accident reports is immediately disclosed to general consumers. In addition, in order to prevent the recurrence of accidents, importers are required to investigate the cause of product-related accidents and take measures such as the voluntarily recall of products when necessary.

### ■ Non-serious product-related accidents must be reported to the National Institute of Technology and Evaluation (NITE).

Information on product-related accidents that are not subject to the System for the reporting and publication of product-related accident information is collected through the NITE accident information collection system. The NITE investigates product-related accidents based on the information collected, identifies cause, and publicizes information on a periodic basis to business operators. Such information includes the cause of accidents and measures designed to prevent recurrence.

#### <Accessing accident information>

##### **Search the NITE Consumer Product Safety Field.**

⇒ <http://www.jiko.nite.go.jp/php/jiko/search/index.php?lang=en>

Accident information from FY1996 can be searched through the NITE website.

##### **Search the accident information databank.**

⇒ <http://www.jikojoho.go.jp/> (Japanese only)

This system unifies information on consumer accidents possessed by the Consumer Affairs Agency, nationwide consumer affairs centers, and other governmental ministries and agencies. This data system is freely accessible by anyone who wishes to search for information on product-related accidents (approx. 95,000 entries as of September 2013).

## Reference ▶ Overseas Safety Marks

Conformity to overseas specifications and standards may be a guide to product safety; however, marks that indicate conformity to overseas specifications and standards do not indicate conformity to Japanese specifications and standards. Therefore, conformity to Japanese specifications and standards must be verified separately.

### CE mark in Europe

The CE mark indicates product conformity to the Essential Safety Requirements (ESRs) specified by EU Directives. Without the CE mark, products cannot be distributed or sold inside the EU.



### CCC mark in China

China Compulsory Certificate (CCC) mark is affixed to products approved by China. Without the CCC mark, products cannot be exported to or sold inside China. This mark is affixed to products meeting safety and electromagnetic compatibility (EMC) standards.



## Topics Four Acts related to Product Safety

Let's take a look at the major Japanese acts and regulations designed to ensure product safety. Four acts have been established to promote product safety. These acts are the Consumer Product Safety Act, the Electrical Appliance and Materials Safety Act, the Gas Business Act, and the Liquefied Petroleum Gas Act.

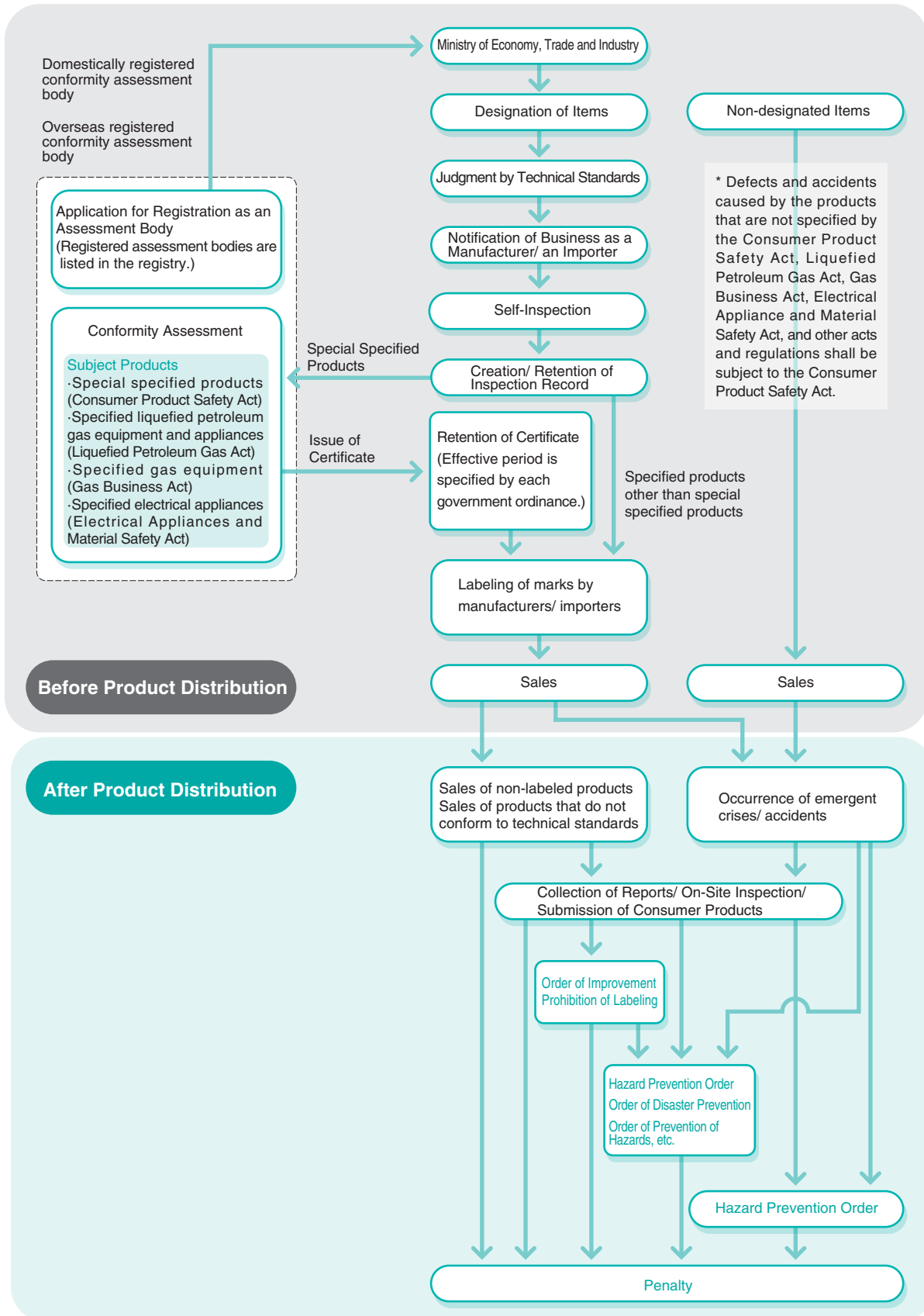
These four acts were established to ensure the safety of general products. The national government designates products subject to each act and indicates technical standards that must be met to prevent harm. Importers of products designated by the acts are responsible for confirming that products conform to the required technical standards and that the products to be sold are labeled as specified by the relevant act. Furthermore, special specified products which have a high potential for harm are required to undergo conformity assessment by registered assessment bodies recognized by the national government.

## Reference ▶ Product Safety (PS) marks based on the four acts related to product safety





# Product Safety System



Source: Ministry of Economy, Trade and Industry website

# 2. The Import and Sale of Food

## Points to Remember for Safety

- The Food Sanitation Act is designed to ensure the safety of imported food, and all food sold or used in business must conform to the specifications and standards contained therein. In order to import food, an import declaration must be submitted to the Quarantine Information Office, Ministry of Health, Labour and Welfare (MHLW).
- In order to prevent the invasion of pests and disease from abroad, fresh vegetables, fruit, meat and meat products must undergo the relevant plant or animal quarantine. Some products from specific regions are prohibited or subject to restrictions.

## Major Import and Sales Regulations

At the time of import	Submission of declaration in accordance with plant and animal quarantine and the Food Sanitation Act Allocation/ approval of imports in accordance with the Foreign Exchange and Foreign Trade Control Act (targeting a segment of fishery products)/ Liquor sales license/ Specified salt retailer, etc.
At the time of sale	Labeling in accordance with the Food Sanitation Act and JAS Act Labeling based on the Measurement Act, Health Promotion Act, and Act against Unjustifiable Premiums and Misleading Representations/ Registration or submission systems for business permission, and license systems for specific products and business forms

## Procedures Specified by the Food Sanitation Act

Procedures stipulated in the Food Sanitation Act must be followed to import products for sale or use in Japan.

### ■ Submission of documents for importing food

Following the arrival of cargo, food import and related documents (depending on the item or items being imported, such documents may include ingredient charts, manufacturing process charts, certificates of sanitation issued by the government of the exporting country, etc.) must be submitted to the MHLW Quarantine Station. The Quarantine Office screens documents, and conducts inspections of the actual products if such is deemed necessary. If the results of the screening and inspections meet the requirements, a certificate of completed declaration is issued. Products cannot be sold or used in business without first completing this procedure.

### Important Points in Screening

- Food products conform to manufacturing standards specified by the Food Sanitation Act.
- Food additives conform to the relevant standards.
- Food products are free of harmful substances.
- Food products from the relevant manufacturer imported in the past have not had any problems involving hygiene.

### Inspections are required when ...

- it is suspected that the imported food violates the Food Sanitation or other act
- the imported food product is subject to monitoring inspection by the national government as stipulated in its annual plan.
- the food product is being imported into Japan for the first time.
- it is determined that sanitation problems may have occurred due to accident during transportation.
- it is determined that safety needs to be assured through inspection due to other reasons.

\*The Quarantine Office gives guidance for voluntary inspection of food imported for the first time.

## ■ Specifications and Standards for Food, Food Additives, etc.

The Food Sanitation Act specifies standards for the production, processing, use, preparation, and preservation of food and food additives, and specifications for ingredients. For example, General Compositional Standards for Food specify that foods shall not contain antibiotics or antibacterial substances and that genetically modified foods shall be screened for safety, and it provides a Positive List of Agricultural Chemical Residues in Food.

In addition, some items such as soft drinks and frozen food products are subject to separate specifications and standards. Due to the fact that milk and milk products require strict sanitation and management, the Ministerial Ordinance on Milk and Milk Products concerning Compositional Standards, etc. specify separate specifications and standards.



### Caution!

#### ● List of foods with separate specifications and standards

The foods listed below have separate specifications and standards. It is necessary to exercise caution to ensure conformity to each of the relevant specifications and standards. For mineral water (in the soft drink category) in particular, there are many specifications and standards that are applied according to the properties of the product, which complicates conformity.

- Soft drinks
- Powdered beverages
- Crushed ice
- Flavored ice
- Meats and whale meat (with the exception of meat and frozen whale meat for raw consumption)
- Beef for raw consumption (except organs)
- Poultry eggs
- Blood, blood corpuscles and blood plasma
- Meat products
- Whale meat products
- Fish-paste products
- Salmon roe or cod roe
- Boiled octopus
- Boiled crab
- Fresh fish and shellfish for raw consumption
- Oysters for raw consumption
- Agar-agar
- Grains, beans and vegetables
- Bean jam for further processing
- Soybean curd (tofu)
- Instant noodles
- Frozen food
- Food packed in containers and sterilized by pressurization and heating

#### ● Confirmation of use of food additives

Food additives that can be manufactured, imported, used, and sold are limited to those designated by the Ministry of Health, Labour and Welfare, excluding existing additives, natural flavoring agents, and general drinks being used as additives. In regard to the use of food additives, ingredient standards that specify purity and form, and use standards that indicate maximum amounts allowed for each food product are provided.

#### ● Agricultural chemical residues in food and pharmaceuticals for animals

Residue standards for agrichemicals in food, feed additives, and drugs for animal use (used for disease prevention and the treatment of livestock and poultry) have been established. Food cannot be imported or sold if residues exceed the allowable limits. In the absence of basic agrichemical standards either in Japan or in the country of origin, the unified standard is set at 0.01ppm.

#### ● Sterilization by irradiation

In principle, food irradiation is prohibited in Japan except for the inhibition of potato sprouts. However, some countries allow irradiation for the sterilization of spices and mushrooms. The Japanese government recommends voluntary inspection to determine whether spices imported from such countries have been irradiated or not.

## ● Cyanide compounds

It is recommended that foods containing natural cyanide compounds, such as flax, apricot, plum, and bitter almond, and products processed from these foods undergo voluntary inspection for cyanide compounds at the time of import. Cyanide levels may not exceed 10 ppm.

### \*What is voluntary inspection?

The national government provides guidance on regularly scheduled voluntary inspections (including the initial time of import) to facilitate voluntary sanitation management by importers. The guidance focuses on the use of agrochemicals and food additives, and violations of the standards and regulations.

### \*Take advantage of preliminary consultation!

Quarantine Offices handling large amounts of imported products have Food Import Consultation Stations that provide advice on individual cases (appointment required). When importing health foods, when importing products for the first time, or if there have been past violations involving the import of the same product or products, it is recommended that importers seek detailed advice through consultation with the specialists at the Quarantine Office.

## Import Quarantine

Quarantine is required for imported products regardless of the amount or purpose, such as individual or business use.

### ■ Plant Quarantine

Plant quarantine applies to all imported plants in accordance with the Plant Protection Act.

Imported products are classified into three categories: imported products to be inspected; imported products not requiring inspection; and import-prohibited products. For the import of plants, including vegetables, fruit, and tea, it is necessary to check the individual classification. Products other than import-prohibited products and those not requiring inspections are subject to import inspection.

Import products to be inspected	Fruit (fresh, frozen, dried), vegetables (fresh, frozen, dried), nuts, grains, pulses, coffee beans (raw), spices, rapeseed, sesame seeds, etc. *Mushrooms are classified as fungi rather than plants; therefore, they are not subject to plant quarantine.
Import products not requiring inspections	Salted, crystallized, and vinegared agricultural products, tea, roasted nuts, designated dried fruits, dried spices in sealed small containers such as bottles and cans.
Import-prohibited products	Products with soil Plants that may cause damage to agricultural products and those that are produced in areas where pests and diseases that are difficult to identify through import inspection exist, such as fresh fruit produced in specific areas.

### ■ Animal Quarantine

Animal quarantine applies to animals and animal products specified for inspection in accordance with the Act on Domestic Animal Infectious Diseases Control. Animals subject to inspection are cloven-hoofed animals, such as cattle and pigs, and poultry, such as chickens. In addition, meat and meat products are subject to inspection. An inspection certificate issued by the relevant government agency of the exporting country is required for the import of such products.

#### Animal products requiring inspection

- Meat, bones, fat, organs, and milk from cloven-hoofed animals (cattle, pigs, sheep, goats, deer), horses, dogs, and rabbits.
- Meat and eggs from poultry (chicken, quail, pheasant, ostrich, guinea fowl, turkeys, ducks, and geese).
- Sausages, hams, and bacons produced from meat of designated products to be inspected.

The import of animals suspected of being affected by foot-and-mouth disease, rinderpest, and African swine fever, and meat, organs, hams, and sausage from such animals is prohibited on a region-by-region basis (excluding products that have undergone heat processing at a certain temperature). In response to the onset of bird flu, Japan has temporarily prohibited poultry imports from some countries.

#### \*Fisheries Quarantine

Some live fishery products require quarantine. In accordance with the Act on the Protection of Fisheries Resources, permission from the Ministry of Agriculture, Forestry and Fisheries is required for the import of juvenile carp, salmon, and Kuruma prawns.

## Food Labeling

Labeling is an important source of information about food content that helps consumers in selecting and understanding how to preserve and use it when purchasing.

Food labeling is specified by municipal ordinances and several acts and regulations, such as the Measurement Act, the Health Promotion Act, and the Act against Unjustifiable Premiums and Misleading Representations, centering on the Food Sanitation Act and Act for Standardization and Proper Quality Labeling of Agricultural and Forestry Products (JAS Act).

### <Major points>

- Processed foods (packaged or wrapped) require lump-sum labeling in accordance with the labeling standards specified by the Food Sanitation Act and Quality Labeling Standards for Processed Foods specified by JAS Act, and labeling in accordance with the Measurement Act.
- Fresh foods require labeling in accordance with the Quality Labeling Standards for Fresh Foods specified by JAS Act. Depending on the property of products, some labeling content must comply with both the Food Sanitation Act and JAS Act.
- Attention must also be paid to other label content such as expiration date, country-of-origin, organic ingredients, allergenic ingredients, genetically-modified ingredients, and nutritional information.



### Topics Safety Assurance for Health Foods

Health food products are included in category of foods. Therefore, it is necessary for such products to conform to the standards and specifications for foods and the appropriate use of additives.

While there are no specifications or standards applied specifically to health food products, measures for safety assurance are in place. Such measures focus on the physical form of such products and whether or not there is experience with them. Newly developed products (those that are not generally known, or that are consumed in ways different for customary food products, for example, tablets and capsules) are prohibited if their safety is in question. Guidelines are provided for products whose ingredients are concentrated in tablet and capsule form to promote the homogenization of product ingredients and safety assurance for raw ingredients.

Furthermore, it is important to distinguish health food products from pharmaceutical products. Health food products cannot contain ingredients that fall under the category of pharmaceutical products, emphasize pharmaceutical effect or efficacy, or come in a form, such as ampoules, that may cause consumers to mistake them for pharmaceutical products. The import and sale of products categorized as pharmaceutical products without permission or approval in accordance with the Pharmaceutical Affairs Act is a violation of the Pharmaceutical Affairs Act.

# 3. The Import and Sale of Cosmetics and Quasi-Drugs

## Points to Remember for Safety

- In addition to drugs and medical devices, cosmetics and quasi-drugs are subject to the Pharmaceutical Affairs Act for the assurance of safety.
- The Pharmaceutical Affairs Act only allows marketing authorization holders and approved manufacturers to import and sell subject items. In addition to the need for products to meet the requirements specified by the acts and regulations, importers must meet the requirements for business approval (the hiring of a pharmacist or other qualified responsible personnel) before they are allowed to import and sell cosmetics and quasi-drugs.
- Even when cosmetics and quasi-drugs are sold as general merchandise, items containing pharmaceutical ingredients or products are subject to the Pharmaceutical Affairs Act.

## Major Import and Sales Regulations

At the time of import	Procedures specified by the Pharmaceutical Affairs Act (Approval for business, Notification of Manufacture, Marketing Authorization Holder, Import, etc.)
At the time of sales	Labeling in accordance with the Pharmaceutical Affairs Act Standards for the Adequate Advertisement of Pharmaceutical Products

### What are cosmetics?

Cosmetics are defined as products that exert mild action on the human body, which are intended to be applied to the human body through rubbing, sprinkling or other means for the purpose of cleaning, beautifying or increasing attractiveness, altering the appearance of or keeping skin or hair in good condition. (e.g. soap, shampoo, conditioner, skincare and makeup products)

### What are quasi-drugs?

Quasi-drugs are defined as treatments, excluding devices, that are milder in effect than regular drugs and used for the purpose of (1) reducing the feeling of nausea or other discomfort, breath and body odor, heat rash, hair loss prevention, and hair growth,; or (2) repelling flies and mosquitoes for human and animal health. (e.g. antiperspirant, hair growers, hair color, bath agents, cosmeceutical products, disinfectants, vitamins, and mosquito mats)

## Cosmetics

### Procedures Specified by the Pharmaceutical Affairs Act

To import and distribute cosmetics, the importer must obtain a License for the Manufacture and Distribution of Cosmetics, or License for the Manufacture of Cosmetics<sup>1</sup>. Furthermore, the manufacturer is required to submit a Notification of the Manufacture and Distribution of Cosmetics for each product in advance and an Application for Accreditation of Foreign Manufacturers and Notification of Import<sup>2</sup>.

Ingredients in cosmetics are specified by the Standards for Cosmetics.

Importers are also required to list specified matters directly on the container or package. Such matters include the name of the product, the manufacturer, and ingredients. The range of effect or efficacy that importers are allowed to claim on products is specified by MHLW notification.

Note 1: License for the Manufacture and Distribution of Cosmetics is a permit to deliver products to market, not to manufacture. Because the Pharmaceutical Affairs Act deems packaging, labeling, and storing to be part of manufacturing, it is necessary to obtain a license for the manufacture of cosmetics, even for the storage of imported cosmetics only. The application should be submitted to the government of the prefecture in which said importer's office is located via the Pharmaceutical Affairs Division of the local government.

Note 2: Place of submission:

- Application for the License for the Manufacture and Distribution of Cosmetics → Pharmaceutical Affairs Division of the local government
- Application for Accreditation of Foreign Manufacturers → Pharmaceuticals and Medical Devices Agency
- Notification of Import → Kanto-Shinetsu Regional Bureau of Health and Welfare or Kinki Regional Bureau of Health and Welfare



## Caution!

### ● Ingredients contained in cosmetics

Cosmetics ingredients must comply with the Standards for Cosmetics. The Standards for Cosmetics specify the prohibition and restriction of ingredients other than preservatives, UV absorbers and tar colors, and the restriction of preservatives, UV absorbers and tar colors. Ingredients are allowed in cosmetics after the safety thereof has been sufficiently confirmed, and such confirmation is the responsibility of the company. All ingredients must be included in the product label.

### ● The range of effect or efficacy of cosmetics

Fifty-six claims such as “cleans scalp and hair” or “makes skin firm,” are specified in the range of effect or efficacy of cosmetics. Manufacturers and distributors are allowed to label makeup effects and feeling of use within the range of these 56 claims. “Reduction/ prevention of wrinkles,” “face-shrinking,” and “reduction of melanin production” exceed the range of effect or efficacy and cannot be used.

## Quasi-Drugs

### ■ Procedures Specified by the Pharmaceutical Affairs Act

Importers must obtain a License for the Manufacture and Distribution of Quasi-Drugs, or a License for the Manufacture of Quasi-Drugs to import and sell quasi-drugs. Overseas manufacturing sites are required to obtain Accreditation of Foreign Manufacturers. Furthermore, the manufacturer is required to obtain an Approval for Manufacture and Distribution for each quasi-drug, and submit a Notification of Import<sup>3</sup>.

Importers are also required to list specified matters directly on the container or package. Quasi-drugs must be labeled as “Quasi-drugs.” The label should be one of three classifications according to its purpose of use: Pest control quasi-drugs; Designated quasi-drugs; and Quasi-drugs.

Note 3: Place of submission:

- Application for the License for the Manufacture and Distribution of Quasi-Drugs, License for the Manufacture of Quasi-Drugs → Pharmaceutical Affairs Division of each local government
- Approval for Manufacture and Distribution of Quasi-Drugs → Pharmaceuticals and Medical Devices Agency/ Pharmaceutical Affairs Division of each local government
- Application for Accreditation of Foreign Manufacturers → Pharmaceuticals and Medical Devices Agency
- Notification of Import → Kanto-Shinetsu Regional Bureau of Health and Welfare or Kinki Regional Bureau of Health and Welfare

## **Caution!**

### **Comparison of specifications between quasi-drugs and cosmetics**

	Cosmetics	Quasi-Drugs
Usable ingredients	Specified by the Standards for Cosmetics.	Approved on a product-by-product basis. Some ingredients have upper limits.
Ingredient labeling	All ingredients should be labeled.	Specified ingredients (those that may cause skin problems such as allergy) must be indicated. The active ingredients of quasi-drugs used for specified quasi-drugs must be indicated.
Range of claims for effect or efficacy	56 claims are specified.	Pharmacological expression is acceptable within the range of effect or efficacy approved. (e.g. "Reducing melanin production helps to prevent spots and freckles caused by exposure to sunlight.")

#### ● **Cosmeceuticals**

So-called "cosmeceuticals" fall into the category of quasi-drugs and require an Approval for Manufacture and Distribution. Attention must be paid to ingredients for which composition standards are designated. Please refer to the List of Active Ingredients in so-called Quasi-Drugs (MHLW)" for the composition of the active ingredients.

The labeling of all ingredients in quasi-drugs is not required; however, all ingredients are indicated on the label based on voluntary industry standards regarding cosmetics.

### **Other Points to Remember**

#### ● **Aerosol products**

Aerosol products in spray cans, such as hair mousse and antiperspirant, passing through Customs are required to have a Certificate of Analysis to show exemption from classification as high-pressure gas products in accordance with the High-Pressure Gas Safety Act. The High-Pressure Gas Safety Act and Fire Service Act require that aerosol products clearly indicate a warning or caution mark such as "Avoid exposure to high temperatures and open flame."

#### ● **The range of private imports**

In principle, import for private use requires that importers submit documents for certification to a Local Bureau of Health and Welfare. As a preferential measure, however, products can be imported upon confirmation by Customs within the range listed below.

##### **[Cosmetics]**

Within 24 units of 1 item in a standard size (e.g. 24 units of lipstick, regardless of brand or color)

##### **[Quasi-drugs]**

External preparations: 24 units of 1 item in a standard size

Other: A 2-month supply as determined by dosage and administration



# 4. The Import and Sale of Home Appliances

## Points to Remember for Safety

- The Electrical Appliance and Material Safety Act is established for the purpose of assuring the safety of home appliances. For the import of electrical appliances, importers are required to ensure the compliance of electrical appliances with the mandatory technical requirements, and to attach PSE marks prior to sale.
- Caution for long-term use must be indicated on five items: electric fans, ventilation fans, air-conditioners, CRT-based televisions, and washing machines (excluding dryers).
- Home appliances fall into the category of consumer products, and importers are required to report any serious product accidents to the Consumer Affairs Agency within 10 days from the day said importers come to know about the accidents. In addition, importers are required to investigate the cause of accidents and take appropriate measures when necessary, such as the voluntarily recall of the products.

## Major Import and Sales Regulations



At the time of import	Notification of Import in accordance with the Food Sanitation Act (targeting equipment that has direct contact with food) Procedures specified by the Pharmaceutical Affairs Act (targeting massage machines, etc.)
At the time of sales	Procedures specified by the Electrical Appliance and Material Safety Act (targeting electrical appliances) Labeling in accordance with the Household Goods Quality Labeling Act (targeting 17 electrical appliances) Reporting serious product accidents Procedures specified by the Radio Act, Water Supply Act

## Procedures Specified by the Electrical Appliance and Material Safety Act

First of all, it is necessary to check whether the home appliance or appliances to be imported fall into the category of electrical appliances. Most electrical products that connect directly to home outlets (457 items) are designated as electrical appliances and subject to the Electrical Appliance and Material Safety Act.

### Importer's Obligations

Electrical appliance importers are required to notify the Ministry of Economy, Trade and Industry of the commencement of business within 30 days from the commencement thereof, comply with the Technical Standards, conduct self-inspections of the finished products, and label them with PSE marks in the prescribed manner. In addition to self-inspections, specified electrical appliances (116 items) are required to undergo conformity assessment by registered assessment bodies.

Specified Electrical Appliances	Non-Specified Electrical Appliances
<p><b>[116 items]</b>                      Electric water heaters                      Electric motor-operated products for children (toys)                      Electric pumps                      Electric massagers                      AC/DC power supply (AC adapter)                      Portable power generators, etc.</p> 	<p><b>[341 items]</b>                      Electric room heaters                      Electric irons                      Pedestal lighting fixtures                      Television receivers                      Other audio equipment                      Secondary lithium ion batteries</p> 

## Items that do not fall into the category of Electrical Appliances and Materials

- Main unit of electrical appliances and materials used with a removable AC adapter  
(However, the AC adapter is included under “AC/DC power supply” and falls into the category of specified electrical appliances and materials.)
- Electrical appliances and materials used with power supply via amplifiers
- A segment of information and telecommunication devices (personal computers, fax machines, , etc.)
- Battery-powered equipment

### Reference

Revision of the acts and regulations on the designation of electrical appliances has been discussed by the national government with the intention of making the range easier to understand, and of promptly corresponding to composite and new products applying advanced technology.

### Compliance with the Technical Standards

Current Technical Standards include detailed specifications regarding the size and form of individual items. However, from January 2014, Specific Safety Guidelines will come into force to clarify the safety performance requirements for each electrical appliance, such as protection for electrocution and maintenance of isolation performance. Current Technical Standards (specifications) will be used as examples for satisfaction of technical requirements.

Importers are responsible for compliance with the Technical Standards. This includes responsibility for self-inspections, asking the foreign manufacturer to carry out inspections and obtaining and verifying the content of inspection records, and the outsourcing of inspections to external organizations.

\*When the approval of the Ministry of Economy, Trade and Industry has been obtained for the manufacture or import of Electrical Appliances and Materials to be used for specific applications, such as models for travelers from abroad, when the import is for experimental purposes, or when the import is exclusively for export, the obligation of compliance is exempted.

\*Overseas safety standard markings such as the CE and UL marks are based on different Technical Standards due to the difference in power distribution systems; therefore, the compliance of products with these marks with the Technical Standards under the Japanese Electrical Appliance and Material Safety Act must be verified.



### Caution!

#### ● Power cord sets and parts for electrical appliances

Dedicated power cord sets included as parts in packages with electrical appliances do not need to be reported or labeled. However, it is necessary that they comply with the Technical Standards as parts or power cord sets.

#### ● Secondary lithium-ion batteries

In response to the increase of smoke and fire accidents, secondary lithium-ion batteries used for laptop computers and mobile phones became subject to the Electrical Appliance and Material Safety Act from November 2008\*. Since July 2012, the range of batteries subject to the Electrical Appliance and Material Safety Act has expanded to include rechargeable batteries with special structures.

\*Note: Subject to the act are batteries whose volumetric energy density per battery is 400wh/L or more, excluding batteries for bicycles, motorcycles, medical equipment and devices, and industrial equipment and devices.

#### ● LED lamps

Some lighting equipment using LED lamps, such as pedestal and decorative lighting fixtures, were already subject to the Electrical Appliance and Material Safety Act; however, from July 2012, LED lamps (in the shape of light bulbs) and LED lighting fixtures were added.

## ■ Long-Term Use Consumer Product Safety Labeling System

Labels for electric fans, air conditioners, ventilation fans, washing machines, excluding dryers, and CRT televisions, excluding those for industrial use, must include the design standard use period and call attention to age deterioration. The Technical Standards include more details.

## Labeling based on the Household Goods Quality Labeling Act

Seventeen electrical appliances subject to the Household Goods Quality Labeling Act must be labeled in accordance with the Quality Labeling Standards for Electrical Appliances.

### Electrical Appliances (17 items)

Washing machines/ Electric rice cookers/ Electric blankets/ Electric vacuum cleaners/ Electric refrigerators/ Ventilation fans/ Air conditioners/ Television receivers/ Electric juice squeezers and blenders/ Electric panel heaters/ Electric kettles/ Electric roasters/ Electric shavers/ Microwave ovens/ Fluorescent desk lamp stands/ Electric cooking heating plates/ Electric coffee makers

## Voluntary Safety Mark

### ■ S Mark

The Steering Council of Safety Certification for Electrical and Electronic Appliances and Parts of Japan (SCEA) established the S Mark System as a private certification system for electrical appliances and materials. Distinct from safety checks conducted by importers, the S Mark is authorized for products whose safety has been certified by the SCEA, and this allows importers to indicate to consumers and distributors that they have achieved standards.



(Labeling combining the S Mark and a certification body logo)

## Other Points to Remember

- Toys that infants may place in their mouth and cooking tools that have direct contact with food, such as coffee makers and mixers, are subject to the Food Sanitation Act.
- Furthermore, there are some items that may be subject to the Radio Act and Water Supply Act, etc.
- Built-in type electric dishwashers, electric dryers for bathrooms, and Electric forced-flue oil-burning air heaters are subject to Long-Term Use Consumer Product Safety Inspection in accordance with the Consumer Product Safety Act.

# 5. The Import and Sale of Gas-Fired and Oil-Burning Appliances

## Points to Remember for Safety

- Among gas-fired and oil-burning equipment for general consumers, designated products are subject to the Gas Business Act, Liquefied Petroleum Gas Act, and Consumer Product Safety Act. To sell these products in Japan, importers must ensure compliance with the Technical Standards, and PSTG, PSLPG, or PSC marks should be affixed to the approved products. Without these marks, products may not be sold in Japan.
- Importers are required to establish an inspection system for products, such as instantaneous gas-fired water heaters and oil-burning air heaters, which carry a high risk of serious product accidents due to age-related deterioration.
- Gas-fired and oil-burning equipment fall into the category of consumer products and importers are required to report any serious product accidents to the Consumer Affairs Agency within 10 days from the day when said importers come to know about the accidents. In addition, importers are required to investigate the cause of accidents and take appropriate measures when necessary, such as the voluntary recall of products.

## Major Import and Sales Regulations



At the time of import	None
At the time of sale	Procedures specified by the Gas Business Act (targeting gas equipment) Procedures specified by the Liquefied Petroleum Gas Act (targeting liquefied petroleum gas equipment) Procedures specified by the Consumer Product Safety Act (targeting 3 oil-burning appliances) Reporting serious product accidents



## Procedures Specified by the Gas Business Act and Liquefied Petroleum Gas Act

### Importer's Obligations

Five items of city gas equipment are subject to the Gas Business Act. Thirteen liquefied petroleum gas (LP gas) equipments are subject to the Liquefied Petroleum Gas Act.

Importers of gas and liquefied petroleum gas equipment are required to notify the Ministry of Economy, Trade and Industry of the commencement of business. Importers are also responsible for confirming that gas and liquefied petroleum gas equipment comply with the required Technical Standards and that the products to be sold are self-inspected and labeled with PSTG or PSLPG marks in the prescribed manner. Specified gas and liquefied petroleum gas equipment is required to undergo self-inspections by importers and conformity assessment by registered assessment bodies.

Specified Gas Equipment	Non-Specified Gas Equipment
<p><b>[4 items]</b> Instantaneous Gas-fired water heaters (semi- sealed types) Gas-fired heaters (semi-sealed types) Bath furnaces with gas burners (semi-sealed types) Bathtub gas burners</p> 	<p><b>[4 items]</b> Gas cooking stoves Instantaneous Gas-fired water heaters (open, sealed, and outdoor types) Gas-fired heaters (open, sealed, and outdoor types) Bath furnaces with gas burners (sealed, outdoor types)</p> 

Specified Liquefied Petroleum Gas Equipment.	Non-Specified Liquefied Petroleum Gas Equipment
<p><b>[7 items]</b>            Cartridge type LP gas cooking stoves            Instantaneous LP gas water heaters (semi-sealed)            Bath furnaces with LP gas burners (semi-sealed)            Bath furnaces            Bathtub burners for LP gas            LP gas heaters (semi-sealed)            LP gas fixtures</p>	<p><b>[9 items]</b>            Regulators            LP gas cooking stoves            Instantaneous LP gas water heaters (open, sealed, outdoor types)            High-pressure hoses with couplings for LP gas            Bath furnaces with LP gas burners (sealed, outdoor types)            LP gas heaters (open, sealed, outdoor types)            LP gas leak alarms            Low-pressure hoses with couplings for LP gas            Antiseismic automatic LP gas breakers</p>
	

 **Caution!**

● **Gas-fired combination water and air heating systems**

In July 2011, the Act was revised to include gas-fired combination water and air heating systems in the category of Instantaneous Gas Water Heaters, which is subject to the Gas Business Act and Liquefied Petroleum Gas Act. Systems placed inside also fall into the category of Long-Term Use Consumer Product Safety Inspection System (indoor type instantaneous gas water heaters).

● **Gas cooking stoves**

Home-use gas cooking stoves are subject to the Gas Business Act and Liquefied Petroleum Gas Act. Technical Standards require all burners to have a safety device to prevent oil from overheating and an automatic burner safety shutoff device to prevent fires caused by gas cooking stoves.

So-called Portable Gas Cooking Stoves/ Cartridge-Type Gas Cooking Stoves are designated as specified LP gas equipment.

**Reference** 

Fuel containers such as gas cartridges used for Portable Gas Cooking Stoves must be labeled with “Caution: Flammable and High Temperature!” as a requirement for exemption from the High Pressure Gas Safety Act.

**Procedures Specified by the Consumer Product Safety Act**

**Obligations of Importers of Specified Products**

Three items of oil-burning equipment (oil water heaters, bath furnaces with oil burners, and oil-burning air heaters, including oil fan heaters) are products specified by the Consumer Product Safety Act.

Importers of specified products are required to submit a notification of commencement of business. Importers are also responsible for confirming that specified products comply with the required Technical Standards and that



Specified Products other than Special Specified Products

the products to be sold are self-inspected and labeled with PSC marks in the prescribed manner.

In order to prevent serious product accidents, the Technical Standards specify the obligation to install a safety device for heating when a low amount of water is present, compliance with standard values for carbon monoxide concentration, and installation of a safety device for incomplete combustion.

### ■ Long-Term Use Consumer Product Safety Inspection System

The Consumer Product Safety Act requires importers to develop an inspection system for specified maintenance products, which pose a high risk of serious product accidents due to difficulty of maintenance by consumers and age-related deterioration. The Act requires importers to submit a notification of business, label products, and manage owners' information in addition to the requirement to conduct inspections.

#### Specified Maintenance Products

Indoor instantaneous gas water heaters (for city gas and LP gas)/ Bath furnaces with indoor gas burners (for city gas and LP gas)/ Oil water heaters/ Oil bath furnaces/ Forced-flue type oil-burning air heaters/ Built-in type electric dishwashers/ Electric dryers for bathrooms



#### Topics Prevention of Product Accidents

According to a METI report\*, nearly 80% of the 1,141 serious product accidents that occurred in FY2010 were caused by electrical and combustion appliances. According to the information on accidents collected by the NITE (including non-serious product accidents), for the four years from 2007 to 2010, home appliances always ranked first followed by combustion appliances, and both home and combustion appliances accounted for approximately 73% of accidents. Manufacturers and importers of these products are required to establish measures to prevent the occurrence and recurrence of serious product accidents.

Reports cite the importance of companies assuming a wide range of use in risk assessment from the design stage and developing safe products to supply to markets, which will lead to the further enhancement of measures for the prevention of accidents.

\*Note: Current Status of Product Safety Measures by the Product Safety Division, Commerce and Distribution Policy Group, Ministry of Economy, Trade and Industry (May 31, 2011)

#### FY2010 Serious Product Accidents Top 5 items by category

	Home Appliances (564 cases)		Combustion Appliances (339 cases)		Other products (238 cases)	
	Item	Number of Cases	Item	Number of Cases	Item	Number of Cases
1	Air conditioners	82	Gas cooking stoves	98	Bicycles	32
2	Electric heaters	42	Oil-burning air heaters	48	Stepladders, stepstools, ladders	19
3	Microwave ovens	35	Oil water heaters	48	Chairs	16
4	Electric refrigerators	31	Gas water heaters	31	Shoes	14
5	Lighting fixtures	22	Gas bath furnaces	23	Child seats for bicycles	13

Based on data provided by the METI

# 6. The Import and Sale of Products for Children

## Points to Remember for Safety

- In order to ensure the safety of products for children, it is necessary to consider child behavior and potential risks.
- There is a risk that infants or children may put toys designed for children under 6 years of age into their mouths. Therefore, such toys are subject to the Food Sanitation Act.
- The use of harmful substances such as formaldehyde in clothes for children is regulated.

## Major Import and Sales Regulations

At the time of import	Notification of Import specified by the Food Sanitation Act (targeting toys for infants, dishes, feeding bottles) Procedures specified by the Explosive Control Act (targeting toy fireworks)
At the time of sales	Regulations for the use of formaldehyde (targeting clothes and bedding material for infants) Labeling based on the Household Goods Quality Labeling Act (targeting clothes, dishes, and feeding bottles) Procedures specified by the Consumer Product Safety Act (targeting baby beds, toys generating laser light) Safety Standards for child seats, etc.

## Safety Regulations for Toys

### Procedures Specified by the Food Sanitation Act

Considering the risk of harm to infants and children, toys targeting infants and children under 6 years of age are regulated by the Food Sanitation Act. Such products must undergo inspection and importers are required to submit a Notification of Import.

### Products subject to the Food Sanitation Act (designated toys)

- Products that will or may come into direct contact with infants' or children's mouths
- Accessories/ Transfer pictures/ Weighted toy tumblers/ Masks/ Origami/ Rattles/ Educational toys (that may be chewed by infants)/ Building blocks/ Toy phones/ Toy animals/ Dolls/ Clay/ Toy vehicles/ Balloons/ Blocks/ Balls/ Toys for play houses
- Products used in combination with the above-listed toys

"Chapter 4 Toys" in the Specifications and Standards for Food, Food Additives, etc. under the Food Sanitation Act specifies standards for toys and the raw ingredients, and manufacturing standards for toys. Specified toys are required to comply with these specifications and standards prior to sale.

### Prevention of accidental ingestion of accessories containing lead

In response to the detection of cadmium in Chinese-made metal accessories for children in the U.S., the Consumer Affairs Agency conducted an investigation. As a result, it was found that some products in Japan also contained levels of lead exceeding the standard values specified by the Food Sanitation Act.

The Consumer Affairs Agency asked the industry to gather information on lead contained in products, reduce the amount used in products, and indicate caution marks.

## ST Mark

The Japan Toy Association specifies Safe Toy Standards for the industry and promotes the use of ST marks on products targeting children up to 14 years of age that meet safety requirements for form, strength, and material safety. The association also established a damage compensation system for accidents caused by products with ST marks.



## Safety of Toy Fireworks

Toy fireworks are subject to the Explosives Control Act\*. Before import, it is necessary to submit an Application for Import Permission and Notification of Import to the prefecture in which the port of importation is located.



The Japan Pyrotechnics Association carries out standard inspections for compliance with the Explosive Control Act, and safety inspections for toy fireworks. Products that meet all the requirements are authorized to display the SF mark. The SF mark is a voluntary industry standard; however, almost all toy fireworks in Japan have SF marks. Products that are authorized to display the SF mark are covered by the compensation system.

**\*Note :** In accordance with the Explosives Control Act, the content of regulations differs according to the classification of products (general explosives, pyrotechnics, toy fireworks, etc.). It is also necessary to check whether or not the imported fireworks fall under the category of toy fireworks. There are regulations for the storage and transportation of explosives (need to store in magazines, need to submit notification of transport, etc.); however, the storage of 25kg or less of gunpowder and explosives contained in toy fireworks, and the transportation of 2 tons or less of gunpowder and explosives are not subject to the regulations.

## Safety Regulations for Clothes

### Regulations for Formaldehyde

Attention must be paid to formaldehyde content in clothing for children. Formaldehyde is often used to prevent shrinkage and wrinkles in clothing. Because of the risk of dermal irritation, however, the Act on Control of Household Products Containing Harmful Substances specifies the allowable amounts. Products that exceed the allowable amount of formaldehyde cannot be sold.

The amount of formaldehyde allowed in clothing for infants aged 24 months or younger is especially strict. Regardless of age, the amount of formaldehyde used for underwear, sleepwear, gloves and socks is also regulated.

### Regulatory Standards for Formaldehyde

Household Products		Standards
Textile Products	(Infants at 24 month old or younger) Diapers/ Diaper covers/ Bibs/ Underwear/ Sleepwear/ Gloves/ Socks/ Intermediate garments/ Outer garments/ Caps and hats/ Bedding material	Upper limit or lower (16ppm or lower)
	Underwear/ Sleepwear/ Gloves/ Socks/ Tabi socks	75ppm or lower
Adhesives	Hairpieces/ False eyelashes/ False beards/ Adhesives for socks	

### Reference

With guidance from the Ministry of Economy, Trade and Industry, voluntary industry regulations specify 1,000ppm or lower for outer garments and 300ppm or lower for intermediate garments for children aged 3 years and older and adults.



#### \*Caution for migration of formaldehyde!

It is easy for formaldehyde to adhere to or be absorbed by other materials through air and moisture. Therefore, while the amount of formaldehyde contained in products may be under the allowable values at the time of production, formaldehyde may migrate from display shelving material where products are placed or stored, or from other non-regulated textile products. Except for samples, therefore, clothing for infants and children should be kept in packages.

\*In addition to formaldehyde, the amounts of dieldrin and DTTB, which are used as mothproofing agents for wool products, contained in clothing are also regulated.

### ■ Children's Clothing Design

Children's clothing must be carefully designed to prevent accidents (entanglement in strings or hoods, accidental ingestion of buttons, etc.). In Europe and the U.S., information on accidents caused by children's clothing is gathered and analyzed to create safety standards for design for the purpose of reducing accidents. In Japan, the Japan Women's and Children's Wear Manufacturers' Association took the lead in establishing Safety Guidelines for the Design of Children's Clothing as voluntary standards for the apparel industry.

## Voluntary Safety Marks

In addition to above-mentioned ST and SF marks, the SG mark is also used to indicate the safety of products for children.



### ■ SG Mark

The Consumer Product Safety Association specifies Safe Goods Standards required for the assurance of safety of consumer products that may pose a risk because of structure or material, and authorizes products that meet SG Standards to display the SG mark. While manufacturers and importers are not required to obtain SG marks, 21 items of infant and children's clothing are currently certified, and the mark has become a guide for consumers in selecting safe products. The SG mark is covered by the compensation system for physical injury due to defects in products authorized to display SG marks.

#### Items covered by the SG Mark (Products for Infants and Children)

Strollers/ Walkers/ Swings/ Slides/ High bars for children/ Tricycles for children/ Pedal cars/ Beds for infants and children/ Slings/ Extendable poles for carp-streamers/ Metal-frame nursery items/ Child safety barriers/ One-person swings/ Baby chairs/ Baby high-chairs/ Playpens/ Portable infant seats for tables/ Baby carriers/ High and low chairs for children/ Child bed guards/ Baby cradles

## Regulations for Other Items

### ■ Safety Regulations for Baby Beds

Beds for infants (up to 24 months of age) are designated as special specified products by the Consumer Product Safety Act. Importers are responsible for submitting a Notification of Commencement of Business, conforming that the products comply with the required Technical Standards, and that the products to be sold are self-inspected, labeled with PSC marks, and undergo conformity assessment by registered assessment bodies.

### ■ Safety Standards for Child Car Seats

Safety Standards for child car seats are specified in accordance with the Road Transport Vehicle Act (Paragraph 5, Article 22, Safety and Maintenance Standards for Road Transport Vehicles), and the Designation System for Device Models is in place as a method of confirming compliance with the standards. Child car seats that meet the standards are authorized to display the relevant designation mark.

# 7. Import and Sales of Other Household Products

## Points to Remember for Safety

- Tools that come into direct contact with foods, such as dishes and cooking equipment, are subject to the Food Safety Act.
- Household pressure cookers and autoclaves, helmets for motor vehicle users, mountaineering ropes, and lighters are designated as specified products by the Consumer Product Safety Act. These products are required to meet the Technical Standards and to display the PSC mark prior to sale.
- Use of harmful substances in household detergent fluids, aerosol products, and textile products such as bedding are regulated.
- Products specified by the Household Goods Quality Labeling Act are required to indicate components, performance, usage, handling precautions, etc.

## Major Import and Sales Regulations

At the time of import	<p>Notification of Import specified by the Food Sanitation Act (targeting equipment that comes into direct contact with foods)</p> <p>Procedures specified by the Pharmaceutical Affairs Act (targeting soaps, toothpaste, hair color, thermometers, manometers, etc.)</p> <p>Procedures required for plant quarantine/ Procedures specified by the Washington Convention and the Wildlife Protection and Hunting Act according to product</p>
At the time of sales	<p>Procedures specified by the Consumer Product Safety Act (targeting specified products)</p> <p>Labeling based on the Household Goods Quality Labeling Act (targeting textile goods, plastic manufactured goods, miscellaneous manufactured goods)</p> <p>Act on the Control of Household Products Containing Harmful Substances (targeting household detergent fluids, household aerosol products, a segment of textile products, household adhesives, etc.)</p> <p>Report of serious product accidents</p> <p>Labeling specified by the Food Sanitation Act and Pharmaceutical Affairs Act according to product</p> <p>Procedures specified by the Fire Service Act, Electrical Appliances and Materials Safety Act, Gas Business Act, Liquefied Petroleum Gas Act, etc. according to product</p>

## Procedures Specified by the Food Sanitation Act

### ■ Safety Regulations for Dishes

Dishes fall into the category of “apparatuses” specified by the Food Sanitation Act, for which importers are required to submit a Notification of Import and undergo inspection. Specifications and standards for dishes are included in Chapter 3. Apparatuses and Containers/ Packages, Specifications and Standards for Food, Food Additives, etc. Products are required to meet said specifications and standards prior to sale. Products in the form of dishes intended for sale as picture plates or stationary articles for ornamental purposes may not be subject to the procedures specified by the Food Sanitation Act.

Dishes made of plastic, reinforced glass, heat-resistant glass, or dishes coated with lacquer or cashew resin must be labeled in accordance with the Household Goods Quality Labeling Act.

\*In addition to dishes, pans, flying pans, cooking apparatuses, water purifiers, and kitchen detergent are subject to the Food Sanitation Act.

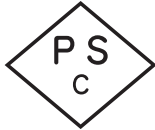

## Procedures Specified by the Consumer Product Safety Act

### Regulations for Specified Products

The Consumer Product Safety Act ensures consumer product safety for products not individually regulated by other acts such as the Food Sanitation Act and Pharmaceutical Affairs Act. In particular, products that pose a risk of injury or death are regulated as specified products.

Importers of specified products are required to submit a Notification of Business Commencement<sup>1</sup>, comply with the required Technical Standards, conduct self-inspections, and label products with PSC marks in the prescribed manner. In addition to these requirements, special specified products are required to undergo self-inspection by importers and conformity assessment by registered assessment bodies.

Note 1: Submission of Notification of Business Commencement requires that importers be covered by Liability Insurance.

Special Specified Products	Specified Products other than the Special Specified Products
<p><b>[4 items]</b>                      Baby beds                      Portable laser-applied equipment (laser pointers, laser aligners, toys emitting laser beams)                      Hot water circulators for bathtubs (whirlpool bathtubs, 24-hour hot water bathtubs, etc.)                      Lighters (disposable and multi-purpose lighters)</p> 	<p><b>[6 items]</b>                      Helmets (for motorbikes, etc.)                      Pressure cookers and autoclaves for home use                      Climbing ropes                      Oil water heaters                      Oil bath furnaces                      Oil-burning air heaters</p> 

### Regulations for Lighters

To prevent accidents resulting from children playing with lighters, disposable and multi-purpose lighters are designated as special specified products<sup>2</sup>. From September 2011, businesses have been prohibited from selling lighters other than those carrying the PSC mark. The Technical Standards specifies height of flame and heat resistance performance, and requires installation of a function that makes it difficult for children to operate (child-resistance function).

Note 2: The term "lighters" here includes home-use equipment that lights articles other than tobacco, and that has a unified structure with fuel containers made from plastic.

## Regulations for Harmful Substances

### Harmful Substances Contained in Household Products

The Act on Control of Household Products Containing Harmful Substances regulates the use of chemical substances such as mercury compounds in household products. To prevent health hazards, the MHLW designates harmful substances for each household product and establishes standards for content, elution and emission. The sale of products exceeding the standard values is prohibited.

In addition to textile products, household detergent fluids, aerosol products, adhesives, paints, wax, shoe polish, wood preservatives, and wood pesticides are also regulated. Attention must be paid to the chemical substances such as wrinkle-resistant and shrink-resistant agents, fungicides, insecticides, flame-proofing agents, and solvents used in these products.

### Harmful Substances (20 items)

Hydrogen chloride/ Sulfuric acid/ Vinyl chloride/ DTTB/ Sodium hydroxide/ Potassium hydroxide/ Tetrachloroethylene/ Trichloroethylene/ APO/ TDBPP/ Triphenyl-tin compounds/ Tributyl-tin compounds/ BDBPP/ Dieldrin/ Formaldehyde/ Methanol/ Organomercury compounds/ Dibenzo[a,h]anthracene/ Benzo[a]anthracene/ Benzo[a]pyrene

\*Household products and harmful substances whose standard values are not specified may not be used freely. If serious damage to health occurs during the use of said products and substances, they must be recalled. Importers and manufacturers are required to prevent health hazards caused by chemical substances contained in home-use products.

### Preventive Measures for Sick Building Syndrome

Chemical substances such as formaldehyde and VOC (toluene, xylene, etc.) that are emitted from building materials used for housing, furniture, and commodities are a cause of sick building syndrome<sup>3</sup>. As a preventive measure, the Building Standards Act limits the use of building materials that emit formaldehyde for the area under the roof and for the interior finishing of rooms. In addition, the use of building materials containing chlorpyrifos (organic phosphorus insecticide for termite control) in residential buildings is prohibited.

Note 3: Sick building syndrome is used to describe situations in which occupants of newly-built or remodeled buildings experience acute health effects such as irritation of the eyes, dizziness, nausea, and headache.

## Labeling based on the Household Goods Quality Labeling Act

The Household Goods Quality Labeling Act designates household products whose quality is extremely difficult for general consumers to discern at the time of purchase, and with respect to which it is determined that there is a particular need to identify quality and ensure proper labeling. Target items are 35 textile goods, 8 plastic manufactured goods, 30 miscellaneous manufactured goods, and 17 electrical appliances. In order to sell these products, they must be labeled in accordance with the individual specifications for quality labeling.

台所用容器	
原料樹脂	ポリプロピレン
耐熱温度	120°C
耐冷温度	-20°C
容量	300ml
取扱い上の注意	
●火のそばに置かないでください。	
●-----	
○○樹脂(株)	
住所 東京千代田区○○町○○番地	

### Indication of “Danger! Don’t mix!”

In response to a fatality caused by the generation of chlorine gas by simultaneous use of acidic detergent and chlorine products, the Household Goods Quality Labeling Act now specifies the display of a warning as a matter requiring special care. Subject detergents and bleaches must indicate such a warning. Matters to be indicated are specified individually for both acidic and chlorine types.

**まぜるな危険**

## Voluntary Safety and Warning Marks

### SG Mark

The Consumer Product Safety Association specifies Safe Goods Standards for 125 items including products for infants and children (see page 23), welfare equipment, furniture and household products, kitchen products, sports and leisure products, home-use fitness products, gardening products, bicycles and bicycle parts, and other items (14 items are currently excluded.) as targets of the SG mark certification system.

## Graphical Warning Symbols for Consumers

The Japanese Industrial Standards (JIS) specify JIS graphical warning symbols for consumers (JIS S 0101) to promote the understanding of warning symbols by consumers. The JIS have no legal force; however, these symbols are specified by the industry for use as warning.



## Regulations for Other Items

### Household Aerosol Products

Although the use of high-pressure gas and containers is regulated by the High Pressure Gas Safety Act, aerosol products such as aerosol containers, gas cylinders for lighters and simplified gas cooking stoves, and gas in refrigerant service cans are exempt from the application of the Act. However, it is necessary to attach inspection results that show compliance with the requirements for exemption from the High Pressure Gas Safety Act at Customs.

In addition, importers are required to indicate warnings such as “Avoid exposure to high temperatures and open flame” in accordance with the High Pressure Gas Safety Act and Fire Service Act.

### Flame Retardant Goods

Curtains and carpets used in high-rise buildings, underground malls, and facilities where unspecified numbers of people come and go, such as theaters, inns, and hospitals, are required by the Fire Service Act to be flame retardant goods.

To be flame retardant here means the characteristic of not burning easily. Flame retardant goods cannot be sold without indicating “Flame Retardant.” Individuals labeling flame retardant goods must be registered by the Commissioner of the Fire and Disaster Management Agency.



### Safety Regulations for Bicycles

Safety Standards for the size, braking devices, and reflectors of bicycles are specified in accordance with the Road Traffic Act, and the Model Certification System has also been established.

The Bicycle Association of Japan established Bicycle Safety Standards as voluntary industry standards to authorize the display of BAA marks on bicycles that meet the standards. Accidents caused by defects in production are covered by PL Insurance, which manufacturers and importers are required to enroll in. Bicycles also have JIS, SG, and TS mark systems which are all voluntary.

# 8. References

Act, Regulations, Procedures	Websites
Procedures Specified by the Food Sanitation Act	Ministry of Health, Labour and Welfare “Imported Foods Inspection Services Home Page” <a href="http://www.mhlw.go.jp/english/topics/importedfoods/index.html">http://www.mhlw.go.jp/english/topics/importedfoods/index.html</a>
Plant Quarantine	Plant Protection Station <a href="http://www.pps.go.jp/english/index.html">http://www.pps.go.jp/english/index.html</a>
Animal Quarantine	Animal Quarantine Service <a href="http://www.maff.go.jp/aqs/english/index.html">http://www.maff.go.jp/aqs/english/index.html</a>
Food Labeling Systems	Consumer Affairs Agency, Government Of Japan “Food Labeling” <a href="http://www.caa.go.jp/en/index.html">http://www.caa.go.jp/en/index.html</a>
Procedures Specified by the Electrical Appliances and Material Safety Act	Ministry of Economy, Trade and Industry “Electrical Appliance and Material Safety Law” <a href="http://www.meti.go.jp/english/policy/economy/consumer/pse/index.html">http://www.meti.go.jp/english/policy/economy/consumer/pse/index.html</a>
Procedures Specified by the Consumer Product Safety Act	Ministry of Economy, Trade and Industry Product Safety Guidelines > For Business Operators (in Japanese) <a href="http://www.meti.go.jp/product_safety/producer/index.html">http://www.meti.go.jp/product_safety/producer/index.html</a>
Procedures Specified by the Gas Business Act	
Procedures Specified by the Liquefied Petroleum Gas Act	
Labeling based on the Household Goods Quality Labeling Act	Consumer Affairs Agency, Government Of Japan “Household Goods Quality Labeling Law” <a href="http://www.caa.go.jp/en/index.html">http://www.caa.go.jp/en/index.html</a>
Act on Control of Household Products Containing Harmful Substances	Ministry of Health, Labour and Welfare “Summary of Criteria for Control of Household Products Containing Harmful Substances” <a href="http://www.nihs.go.jp/mhlw/chemical/katei/PDF/120326_list_eiyaku.pdf">http://www.nihs.go.jp/mhlw/chemical/katei/PDF/120326_list_eiyaku.pdf</a>
Procedures Specified by the Pharmaceutical Affairs Act	Tokyo Metropolitan Institute of Public Health (in Japanese) “Drugs, Quasi-Drugs, Cosmetics Screening” <a href="http://www.tokyo-eiken.go.jp/k_yakuji/i-sinsa/">http://www.tokyo-eiken.go.jp/k_yakuji/i-sinsa/</a> Manufacture and Distribution of Medical Devices, Manufacture and Repair of Medical Devices, Specially Controlled Medical Devices” <a href="http://www.tokyo-eiken.go.jp/k_iryuu/k-sinsa/kikikyokanituite/">http://www.tokyo-eiken.go.jp/k_iryuu/k-sinsa/kikikyokanituite/</a>
Import Clearance Procedures	Japan Customs <a href="http://www.customs.go.jp/english/index.htm">http://www.customs.go.jp/english/index.htm</a>

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November 2013