Информация относно изисквания за внос, процедури и регистрационен режим при експорт/ импорт на козметични продукти през 2022 г. в Япония.

B. Beauty products as defined by the Japanese law

1. Legal definition of a cosmetic item

In Japan, cosmetics are regulated by the Ministry of Health, Labour and Welfare (MHLW) under the Pharmaceutical Affairs Law (PAL). For legal purposes, beauty products are divided into quasi-drugs and cosmetics.

a. Cosmetic from a legal point of view

The law defines cosmetics as "articles with mild action on the human body, which are intended to be applied to the human body through rubbing, sprinkling or other method, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition." On the Japanese market, cosmetics are furthermore classified into 6 different categories, as below:

Item	Definition	HS Code
Perfume and eau de cologne	Perfume and eau de cologne	3303
Makeup cosmetics	Foundation creams, lipsticks, eye makeup, and others	3304.10, 2, 30, 91
Skin care cosmetics	Skin lotion, essence, skin milk, cleansing cream, and others	3304.99
Hair care products	Hair dye, shampoo, hair treatment and others	3305
Special-purpose cosmetics	Sunscreen, shaving cream and others	3307.10, 20, 30, 90
Cosmetic soaps	Soaps for cosmetics	3401.11, 20-010

b. Quasi-drugs from a legal point of view

As stated above, beauty products are classified into two categories in Japan by the MHLW: cosmetics and quasi-drugs. There regulations differ slightly but the difference between cosmetics and quasi-drugs remains ambiguous. In practice, this distinction is made based on differences in the effects assigned to each product. The distinction is also influenced by a set of criteria, such as the nature and the quantity of ingredients used, application method, dosage, and appearance of the product.

The PAL defines "Quasi-drug" (医薬部外品) as an item for the purpose of: (1) Preventing nausea and other discomfort. (2) Preventing heat rash, soreness, etc. (3) Encouraging hair growth or removing hair, or (4) Exterminating and preventing mice, flies, mosquitoes, fleas, etc. Among the quasi-drugs are deodorants, depilatories, hair growth treatments, hair dyes, perm and straightening products, as well as medicated cosmetics, such as whitening products, anti-aging products and oily skin or acne treatment products.

Besides, the item shall have mild effects on the human body, shall not be a utensil or device, and shall be designated by the MHLW based on these characteristics. The chapter C.2.f deals with the importation specificities of quasi-drugs.

C. Importing cosmetics to Japan

1. Importation flow

When considering selling products in Japan, the first step is to ensure that the products are in accordance with the law and will be legal in Japan. This assessment is performed on samples of the products by "testing and inspection facilities" designated by the MHLW, owned or contracted by the importer. It basically consists on checking the list of ingredients and analyzing the components of cosmetics to make sure it is in compliance with the PAL.

To better understand the full implications of the PAL, it is crucial to understand that importers of cosmetics assume all quality assurance and product liability for cosmetics. Consequently, it is necessary for them to be ready to take full responsibility for imported cosmetics through regulation analysis and safety testing, even though those items were already fully tested and are legal in the home country.

Once the formula have been checked and products have been tested, the importer will fill 3 forms: a Manufacture and Sales of Cosmetics Notification, a Cosmetics Import Notification for Manufacture and Sales and the manufacturer's or importer's brand name. Those forms will contain a record of the testing and inspection results verifying that the product does not contain any prohibited combination. The products is now ready to be sent to Japan where the importer will handle the clearance.

Advertising and labeling for cosmetics are regulated by law, which details labeling guidelines for containers or packaging, and certain items that may not appear in the labeling. Products that violate labeling regulations are deemed improperly labeled, and their sale is prohibited. The law also requires that the container, packaging or package inserts of cosmetics be specifically labeled to ensure appropriate use, handling and quality, and clarify liability. All information must be clearly and explicitly expressed in Japanese, and labeling with false or potentially misleading statements and unapproved claims of effects/efficacy are prohibited. As importers assume all quality assurance and product liabilities, they impose an inspection of every single item to check the packaging, to add a label in Japanese and possibly repacking the product. This inspection procedure usually takes place in their own facilities. The products, now fully legal, can be dispatched to the company responsible for distribution (distributor, agent, etc.).

2. Notifications and licenses

It is entirely possible for an exporting company to handle the importation or distribution of its products themselves by opening a local subsidiary for example. In this case, the local company should follow specific regulations and procedures to be able to act as an importer or a distributor.

a. Approval for primary distribution by product category

The Cosmetics Standards (Ministerial Notification in September 2000) defines the ingredients that are subject to prohibition or restriction in cosmetics combinations, and those that are allowed in cosmetics combinations in specific ingredient groups. Antiseptics, ultraviolet ray absorbents and tar coloring are subject to a positive list that indicates the maximum mixture quantities. All other ingredients may be used in cosmetics combinations after the safety verification and selection at their own liability, except those covered by a negative list of

combinations that either prohibits or limits them. In this regard, however, all ingredient names must be listed in the labeling.

If the provided ingredients do not violate the Cosmetics Standards and all the ingredients are indicated on the labeling, approval for primary distribution by product item is not required. However, products containing amounts of ingredients in excess of the notifiable limit, or new ingredients without a history of prior usage, or which contain non-disclosed ingredients, must obtain primary distribution approval for each product item.

b. Cosmetics manufacturing and sales license

Under the provisions of the revised PAL, which went into effect as of June 1, 2009, when importing and distributing cosmetics, the importer must obtain a cosmetics manufacturing and sales license (化粧品製造販売許可). The sales business refers to the act of selling, renting, or lending of manufactured (including delegated to another, but not including manufacturing conducted for another) or imported cosmetics. Consequently, companies that do not possess their own manufacturing facilities may still obtain a license.

In order to obtain or renew this license, it is necessary to establish within the company a product safety and quality management system, consisting in naming three person in charge (a Marketing Supervisor, a Quality Supervisor and a Safety Control Supervisor) responsible for checking the compliance of imported cosmetics with Japanese regulations, quality assurance and product safety, those person in charge must be independent of the sales section. One person can be appointed for those 3 responsibilities. Those persons have to implement a set of standards called Good Quality Practice (GQP) and a Good Vigilance Practice (GVP), as well as undertake appropriate actions for safety management.

After obtaining a business code number in advance, applicants must include with their submission:

- a copy of the corporate registration (in the case of a corporation);
- a list of duty specifications;
- a medical certificate specifying the applicant;
- documents certifying the qualifications of the marketing supervisor-general;
- an employment contract of the marketing supervisor-general;
- documents disclosing the quality management system;
- documents disclosing the post-marketing safety management system;
- a floor plan of the business office and storage facility.

The cosmetics manufacturing and sales license applications are filed with the competent prefectural pharmaceutical affairs division with jurisdiction over the business office where the marketing supervisor-general serves and the licenses are to be renewed every five years.

c. Notifications

After obtaining the cosmetics manufacturing and sales license but before initiating product importation, the importer must, as stated above, fill 3 notifications to the proper administrative agency:

Notification	Administrative agency responsible
Manufacture and Sales of Cosmetics Notification	Same prefecture as that which has granted the cosmetics manufacturing and sales license
Cosmetics Import Notification for Manufacture and Sales	Kanto-Shinetsu Regional Bureau of Health and Welfare (Tokyo) or the Kinki Regional Bureau of Health and Welfare (Osaka)
Manufacturer's or importer's brand name	Pharmaceuticals and Medical Devices Agency, Japan (Tokyo)

These notifications must either be accompanied by an ingredient listing from the importer's supplier or manufacturer or, if this list cannot be obtained, a record of the testing and inspection results confirming the product does not contain any prohibited ingredient combinations.

d. Cosmetic manufacturer's license

According to the PAL, any importer that engages in the final packaging, labeling in the Japanese language, or storage of the imported product, is required to obtain a cosmetic manufacturer's license (化粧品製造許可). Therefore, even if the product was already labeled overseas in Japanese and no packing process is necessary, the importer of that product still must obtain a cosmetics manufacturer's license (in addition to obtaining a cosmetics manufacturing and sales license) because the product must be temporarily stored in a facility during the tests or clearance process. However, the cosmetic manufacturer's license should be obtained under a classification of "packaging, labeling, and storage only", excluding the case of manufacturing that is delegated to another licensed manufacturer.

Application for such a cosmetic manufacturer's license requires:

- an outline of the physical facility;
- a floor plan of the manufacturing facility;
- documents certifying the qualifications of the responsible engineer;
- the employment contract of the responsible engineer;
- a copy of the contract with a testing laboratory (when used)

e. Good Quality Practice (GQP) and Good Vigilance Practice (GVP)

As part of the GQP, importers are required to properly evaluate their production management and quality control of cosmetics to be distributed. It consists in establishing a procedures manual for the registration of product delivery, collection of information on the quality of products, processing of defective products, products' withdrawal from the market, etc. This standard aims at maintaining the quality of products that are marketed by the license holder.

Additionally, importers of cosmetics must establish systems that are capable of providing and retaining accurate information in response to consumer inquiries along with a monitoring system that handles customer complaints over product quality and product recalls, as required by the GVP standards. This consists in collecting information relating to the safety of products provided by the competent authorities, professional

organizations, manufacturers, retailers, consumers, researchers, etc. After analysis of these information and if deemed necessary (possibility of harmful effects caused by the products, for example), the importer may undertake corrective actions such as the withdrawal of products from the market or changing warnings and precautions for use on packaging. Furthermore, if the license holder becomes aware of any information indicating that one of the imported cosmetic product may have a harmful effect, they must report that fact to the MHLW within 30 days.

f. Special case of quasi-drugs

As stated in chapter C.2.a, the approval for primary distribution is not always necessary for cosmetics, however, this pre-approval is mandatory in the case of quasi-drugs because they contain active ingredients that need to be approved by the MHLW. Pre-approval is granted by the competent authorities if they judge that the product answered all sanitary requirements. Items such as formula, manufacturing method, application method and claimed effects are checked on this occasion.

Having an active ingredient approved by the MHLW allows the product to display its effectiveness for a result that has yet to be recognized. This allows companies to indicate that the product is "Medicated." This process takes approximately six month for the MHLW to carry out the appropriate examination.

g. Requirements on aerosols products

Aerosol products (e.g., hair spray) must be separately inspected at the time of importation if the relevant products meet certain requirements specified under the High Pressure Gas Safety Act. However, they will be excluded from the application of the Act on condition that the product described precautions on usage for consumers and if written results of tests certifying that the products do not fall under the PAL are submitted to customs.

If no such documentation is submitted or if the tests for any item fail, an inspection by the competent prefectural governor is required.

h. Requirements on sunscreens

In Japan, sunscreens are classified as quasi-drugs, therefore, they require approval of their formulations, ingredients, use levels and functionalities, in addition to stability testing and a certificate showing no animal-derived materials were used. Product evaluations should be based on ISO 24442 in vivo testing and labeling. Also, an SPF of 50+, corresponding to PA++++, is the maximum level allowed on the label.

3. Labeling

When selling cosmetics, the PAL requires that the container, packaging, or package inserts of cosmetics to be labeled with a list of specified items, depending on the type of products and container as listed in this chapter. Those laws aim to ensure appropriate usage, handling and quality of the product as well as clarify liabilities.

All the information must be expressed in Japanese and must be clearly and explicitly listed. Labeling with false or potentially misleading expressions, and unapproved claims of effect-efficacy in labeling are prohibited. The items that should be indicated for cosmetics are as follows:

Item	Description
Name and address of importer	Address of the office where the Marketing Supervisor serves (if this office is outside Japan: name and country of foreign approval holder; name and address of the nominated importer).
Brand name	Name for which notification has been posted for importation.
Manufacturing number or code	
List of ingredients	In principle, all ingredient names shall be listed on the label, in Japanese, and must be listed in descending order by quantity.
Expiration date	
Other items specified by the MHLW Ministerial Ordinance	

Note for ingredients: The Japan Cosmetic Industry Association (JCIA) has compiled a Japanese version of the "List of Cosmetic Ingredient Label Names" to be used in conjunction with the Pharmaceutical Affairs Act's requirement to list all ingredient names on the labeling (this list is available in Japanese only here: http://www.jcia.org/n/all_pdf/gul/mgl.pdf). If a new label name needs to be devised, then a request can be filed with the JCIA. Label names shall be, in principle, translated into Japanese from the International Nomenclature of Cosmetic Ingredients (INCI) names published by the Cosmetic, Toiletry, and Fragrance Association (CTFA) of the United States.

a. Act against Unjustifiable Premiums and Misleading Representations

The PAL prohibits any form of improper labeling with exaggerated or false labeling that misleads consumers about the nature or quality of a product. To prevent it, the Consumer Affairs Agency (CAA) may require documentation, for labeling that makes claims of superior quality etc., which attest those claims to be true. If the importer, distributor or retailer is unable to do so, those claims are considered to be a form of improper labeling and must be withdrawn. Vague or confusing labeling regarding the country of origin is also prohibited as a form of improper labeling.

Based on the Act, the industry of cosmetics has adopted the Fair Competition Code Concerning Representations of Cosmetics, the Fair Competition Code Concerning Representations of Cosmetics Soaps, and the Fair Competition Code Concerning Restrictions on Premium Offers in the Cosmetic Soap Industry, under certification by the Consumer Affairs Agency. While these are voluntary industry rules, when they are adopted based on the Act, any breach of the Fair Competition Code is deemed to be as a breach of the PAL. The required labeling items for cosmetics and cosmetic soaps are as follows.

For cosmetics:

- Product name by type
- Brand name
- Name and address of primary distributor
- Content (weight or capacity)
- Country of origin
- Manufacturing number or code

- List of ingredients as required by the MHLW
- Expiration date, for a cosmetic designated by the MHLW
- Precautions on usage or storage
- Information contact

For soaps:

- Name and address of primary distributor
- Brand name
- The word "Soap"
- List of ingredients as required by the MHLW
- Manufacturing number or code
- Expiration date, for a designated cosmetic soap
- For those products manufactured by a frame mixing method, a term to that effect
- Standard weight per unit
- Country of origin

If you need any more information, here is the list of contacts:

- Cosmetic Fair Trade Council: +81-3-5472-2533
- Cosmetic Soaps Fair Trade Council: +81-3-3271-4301

b. High Pressure Gas Safety Act and Fire Service Act

In the case of aerosol products and products deemed hazardous, the High Pressure Gas Safety Act and the Fire Service Act defines information to appear on the label, such as warnings, cautions, types and quantities of hazardous materials, and the size of the letters and other labeling practices. Here is an example of a typical representation:

Keep away from fire and high temperatures

This is combustible product using high-pressure gas. Be sure to observe the following:

1. Do not use near flames or fire.
2. Do not use large amounts in rooms with open flames.
3. The container may burst if exposed to high temperatures. Do not place under direct sunlight or near fires or other locations of temperatures more than 40°C.
4. Do not dispose of in incinerator.
5. Be sure to use completely before disposal.

High Pressure Gas: Type of gas used (label name of gas)

c. Law for Promotion of Effective Utilization of Resources

Under the Law for Promotion of Sorted Collection and Recycling of Containers and Packaging, when paper or plastic is used as a packaging material for the wrapping of individual product items, a material identifier mark must be displayed in at least one location on the side of the container, in order to promote sorted collection. Here is an example of typical representations for paper (left) and plastic (right):

d. Voluntary labeling by the Aerosol Industry Association of Japan

The Aerosol Industry Association of Japan has established labeling guidelines for aerosol products. This is an example of precautions on usage:

- Do not place heat-sensitive objects near heating devices, as there is a risk of high temperatures leading to rupturing.
- To dispose of the product, take it outdoors to a location away from all flames, and press the button until the hissing sound stops, in order to exhaust all the gas.

If you need any more information, here is the contact information:
Aerosol Industry Association of Japan: +81-3-3201-4047 http://www.aiaj.or.jp

4. Costs of importation

a. Formula check and product analysis

Taking place in the testing laboratory of the importer, the price per item differs greatly depending on the laboratory, product type and complexity of the formula. However, the price is usually **between 30 000 JPY and 70 000 JPY** (200 euros and 500 euros).

The analysis itself aims to ensure the conformity of the products with the Japanese legislation. To do so, the following items are to be tested: preservatives, UV absorbents, anti-oxidants, heavy metals, Japanese legal color index colorants, prohibited ingredients. Also, some specific test could be perform: pH, viscosity, specific gravity, bacterial count, patch tests, stability tests and more.

b. Notifications and customs clearance

This step is handled by the importer, as the cosmetics manufacturing and sales license is required.

c. Labeling, packing and product inspection

For 5 items, the price for the design of the label is around **20 000 JPY** (140 euros) while the printing is around **500 JPY** (3 euros) for 100 labels. Regarding the inspection and labeling, the price is around **70 JPY** (50 cent of euro). This step is also handled by the importer, as the cosmetic manufacturer's license is required.

d. Special case of quasi-drugs

The importation of quasi-drugs is much more expensive than cosmetics, the whole price, including the various tests, notifications, approbations and so on, could be as high as **few million JPY** (tens of thousands euros).

e. Tariff duties on cosmetics

Below is the list of tariffs imposed on cosmetics:

HS Code		Description	Rate of duty		
					EU
3303.00	000	Perfumes and toilet waters			Free
3304		Beauty or make-up preparations and preparations for the care of the skin (other than medicaments), including sunscreen or suntan preparations; manicure or pedicure preparations			
10		Lip make-up preparations			Free
20		Eye make-up preparations			Free
30		Manicure or pedicure preparations			Free
		Other			
91		Powders, whether or not compressed			Free
	010	Toilet powders			
	090	Other			
99		Other			Free
		Creams and other preparations with a basis of oil, fat or wax			
	011	Foundation creams			
	012	In liquid form			
	019	Other			
	090	Other			
3305		Preparation for use on the hair			
10		Shampoos			Free
20		Preparations for permanent waving or straightening			Free
30		Hair lacquers			Free
90		Other			Free
	010	Perfumed hair oil, cream, pomade and other preparations with a basis of oil, fat or wax			
		Other			
3307	090	Pre-shave, shaving or after-shaving preparations, personal deodorants, bath preparations, depilatories and other perfumery (excluding articles relevant to other items)			
10		Pre-shave, shaving or after-shave preparations			Free
20		Personal deodorants and antiperspirants			Free
30		Perfumed bath salts and other bath preparations			Free
90		Other			
	010	1. Preparations with a basis of oils, fats or waxes			Free
	090	2. Other			Free
3401		Soap; organic surface-active products and preparations for use as soap or washing the skin, in the form of liquid or cream and put up for retail sale			
11		For toilet use (including medicated soap)			Free
20		Soap in other forms			
	010	For toilet use (including medicated soap)			Free

Note 1: Refer to "Customs Tariff Schedules of Japan" (https://www.customs.go.jp/english/) for a more complete interpretation of the tariff table and for more details on Economic Partnership Agreements (EPAs) with each country.

5. Contacts of Competent Authorities

Related regulations and control	Competent agencies	Contact/Website
Pharmaceutical Affairs Act	General Affairs Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (Pharmaceutical Affairs Act in general)	+81-3-5253-1111 http://www.mhlw.go.jp
	Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (Marketing approval procedures)	+81-3-5253-1111 http://www.mhlw.go.jp
High Pressure Gas Safety Act	Industrial Safety Division, Nuclear and Industrial Safety Agency, Ministry of Economy, Trade and Industry	+81-3501-1511 http://www.nisa.meti.go.jp
Fire Service Act	Fire and Disaster Management Agency Fire Station having jurisdiction over the address	+81-3-5253-5111 http://www.fdma.go.jp
Act against Unjustifiable Premiums and Misleading Representations	Representation Division, Consumer Affairs Agency	+81-3-3507-8800 http://www.caa.go.jp
Act on Specific Commercial Transactions	Consumer Economic Policy Division, Commerce and Information Policy Bureau, Ministry of Economy, Trade and Industry	+81-3-3501-1511 http://www.meti.go.jp
Law for Promotion of Effective Utilization of Resources/Law for Promotion of Sorted Collection and Recycling of Containers and Packaging	Recycling Promotion Division, Industrial Science and Technology Policy and Environment Bureau, Ministry of Economy, Trade and Industry	+81-3-3501-1511 http://www.meti.go.jp
	Office of Recycling Promotion, Policy Planning Division, Waste Management and Recycling Department, Ministry of Environment	+81-3-3581-3351 http://www.env.go.jp

D. Appendix

1. Table of reference

[1] Ministry of Health, Labour and Welfare, "Pharmaceutical Affairs Law", 1943

[2] Ministry of Health, Labour and Welfare, "Ordinance No. 30/1966" and its amendments, 1966

[3] Ministry of Health, Labour and Welfare, "Notification No. 166/1980", 1980

[4] Ministry of Health, Labour and Welfare, "Guide to Quasi-Drug and Cosmetic Regulations in Japan", published by Yakuji Nippo, 1992

[5] Ministry of Health, Labour and Welfare, "Ordinance No. 125/2000", 2000

[6] Ministry of Health, Labour and Welfare, "Notification No. 1339/2000", 2000

[7] Ministry of Health, Labour and Welfare, "Notification No. 330/2000", 2000

[8] Ministry of Health, Labour and Welfare, "Notification No. 331/2000", 2000

[9] Ministry of Health, Labour and Welfare, "Notification No. 332/2000", 2000

[10] Pharmaceutical and Medical Safety Bureau, "Notification No. 990/2000", 2000

[11] "The Comprehensive Licensing Standards Of Cosmetics by Category", published by Yakuji Nippo, 1994

[12] "The Japanese Standards of Cosmetic Ingredients", 2nd Edition, published by Yakuji Nippo, 1985

2. List of abbreviations

CIF: Cost, Insurance, Freight

CAA: Consumer Affairs Agency

CTFA: Cosmetic, Toiletry, and Fragrance Association

EPA: Economic Partnership Agreement

GQP: Good Quality Practice

GVP: Good Vigilance Practice

INCI: International Nomenclature of Cosmetic Ingredients

ISO: International Organization for Standardization

JCIA: Japan Cosmetic Industry Association

MHLW: Ministry of Health, Labour and Welfare

PA: Protection Grade of UVA

PAL: Pharmaceutical Affairs Law

SPF: Sun Protection Factor

WTO: World Trade Organization

3. List of English-Japanese translations

Cosmetic: 化粧品

Cosmetics Import Notification for Manufacture and Sales: 製造販売用化粧品輸入届書

Cosmetic manufacturer's license: 化粧品製造許可

Cosmetics manufacturing and sales license: 化粧品製造販売許可

Manufacture and Sales of Cosmetics Notification: 化粧品製造販売届出

Quasi-drugs: 医薬部外品

4. List of tables

5. Standards for Cosmetics

Below is the link to the "Standards for cosmetics (Ministry of Health and Welfare Notification No.331 of 2000)" containing positive lists and negative lists of ingredients for cosmetics. If an ingredient does not violate the provisions of the "Standard for Cosmetics", it is permitted to incorporate it in cosmetics after checking and choosing safety under corporate responsibility.

Here is the list of information included in the "Standards for cosmetics, Notification No. 331/2000", please use as reference if in search for the legality of a specific ingredient in Japan. It can be downloaded here in English: http://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/0000032704.pdf.

	Ingredients Class	Ingredients
Prohibition of inclusion	Other than preservatives, UV absorbers and tar colors	Refer to the appendix 1 of page 3
Limitation on inclusion	Other than preservatives, UV absorbers and tar colors	Refer to the appendix 2 of page 4
	Preservatives	Refer to the appendix 3 of page 5
	UV absorbers	Refer to the appendix 4 of page 7
	Other than tar colors	Shall apply the provisions of Article 3 of the ministerial ordinance to specify the tar colors that can be used for medical supplies, which is No. 30 of the Ordinance of the Ministry of Health and Welfare 1966.