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# Report Name: The Japanese Market for CBD and Hemp Extracts

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#### **Report Highlights:**

The aim of this report is to inform potential U.S. exporters of cannabidiol (CBD) products about relevant import regulations and market opportunities in Japan.

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# **1. Introduction**

The aim of this report is to inform potential U.S. exporters of cannabidiol (CBD) products about relevant import regulations and market opportunities in Japan. Meros Consulting researched and prepared this report between May and June 2021 by taking a deep dive into desktop resources on the regulatory situation and interviewing a variety of government and business players in Japan's CBD product market. It is a rapidly evolving market and changes in regulations, laws and requirements can be expected for various CBD products in the next several years.

For information on Japanese regulations for hemp fiber and hemp seed products, please see reports titled *The Japanese Market for Hemp Fiber* and *The Japan Market for Hemp Seed and Hemp Seed Oil Products* respectively. For further details on import regulations and processes for exporting food products to Japan, please refer to <u>FAS's Import Regulations and Export</u> <u>Guides for Japan</u>, which provides information by food product type.

#### Disclaimer

This report was created for general information purposes only. While every effort has been taken to ensure accurate information at the time of publication, laws and requirements around hemp-derived products can change quickly. In addition, there are differences between U.S. and Japanese regulations for hemp-derived products. FAS/Tokyo encourages U.S. exporters to work closely with their importers as they develop their export plan for Japan.

Professional advice should be sought for any specific matters of concern and all information contained in this report should be re-confirmed with importers and competent authorities. This report contains translations prepared by various government agencies, as well as Meros. However, only the original Japanese texts of the laws and regulations have legal effect, and the translations are to be used solely as reference materials to aid in the understanding of Japanese laws and regulations.

For further questions about hemp regulations, please contact FAS/Japan at AgTokyo@fas.usda.gov

#### **Terms Used**

Under Japan's legal regulatory framework, the Cannabis Control Act defines 'cannabis' as "the cannabis plant (*Cannabis sativa L.*) and its products". The Cannabis Control Act bans importation of "cannabis". However, mature cannabis stalks and products made from stalks (excluding resin, which is illegal), as well as cannabis seeds and products made from the seeds are excluded from this legal definition of "cannabis". Japan has a zero-tolerance level for tetrahydrocannabinol (THC) in any product.

In marketing and discussion of the *Cannabis sativa L*. plant and its products, the Japanese language has a number of words that are used in different contexts, including *taima*, *asa*, and *henpu*. However, to maintain consistency in this report, we use the word **cannabis** throughout this report to refer to all parts of the *Cannabis sativa* L. plant. We use the word **hemp** to refer to the parts of the plant and its products which are legally allowed to be marketed in Japan, including hemp fiber, hemp seed oil or hemp extract.

# Glossary

This glossary outlines some of the key terms as used in this report.

Word	Definition
Cannabis	Cannabis to refers to the plant Cannabis sativa L.
Hemp	Hemp refers to the parts of the cannabis plant that may be legally marketed and imported, specifically mature stalks (excluding resin) and cannabis seeds and their products.
Cannabinoids	Naturally occurring compounds found in cannabis plant (e.g., THC, CBD and CBG).
THC (Tetrahydrocannabinol)	The principal psychoactive constituent of cannabis.
CBD (Cannabidiol)	One of the best-known cannabinoids.
CBG (Cannabigerol)	A non-psychoactive cannabinoid found in small quantities in cannabis plants.
CBN (Cannabinol)	A non-intoxicating cannabinoid created when THC breaks down after prolonged periods of time.
CBD isolate	Purest form of CBD; does not contain any other cannabinoids, terpenes, fats, lipids or other compounds found in the cannabis plant. CBD isolate is a white, powdery solid that is typically 99+ percent CBD.
CBD distillate	Highly refined extract that has undergone the distillation process. CBD distillate is a golden, viscous oil that typically contains around 70-80 percent CBD, and includes other cannabinoids. In Japan, CBD distillate is available principally as broad-spectrum distillate.
Broad-spectrum CBD	Indicates an extract that contains all cannabinoids and other plant compounds found in the cannabis plant, but typically should not contain THC. In the Japanese market, products are sometimes labeled "full spectrum CBD," but contain no THC.

Synthetic CBD	CBD made in a lab and is chemically identical to CBD from <i>cannabis</i> . Sugarcane and citrus are some base raw material sources reportedly used.
Hemp extract	Oil extracted from the leaves, stems and seeds of the cannabis plant; can contain a wide range of possible compounds including cannabinoids, terpenes, flavonoids and other compounds. The term " <b>hemp extract</b> " as well as the term " <b>hemp oil</b> " are both seen in the Japanese market for products marketed as containing CBD. However, in other cases hemp products with no CBD are also marketed as hemp extract and hemp oil.
Hemp seed oil	Oil extracted from cannabis seeds.

# 2. General Background

## 2.1. Legal Framework

The Cannabis Control Act bans importation of cannabis. However, mature cannabis stalks and products made from stalks (excluding resin, which is illegal), as well as cannabis seeds and products made from the seeds are excluded from the legal definition of "cannabis".

Japan has zero tolerance policy for THC. The Cannabis Control Act does not explicitly mention THC. However, in practice, the Ministry of Health, Labour and Welfare (MHLW) interprets the presence of THC to mean that parts of the cannabis plant other than the mature stalks<sup>1</sup> and seeds were used. Unacceptable parts include flowers, buds, leaves, immature stalks, or roots. A product derived from the cannabis plant that has detectable THC would therefore be in violation of the Cannabis Control Act due to the assumption that it must have been derived from parts of the plant other than mature stalks and seeds.

Meanwhile, chemically synthesized THC is explicitly banned under the Narcotics and Psychotropics Control Act. The Narcotics and Psychotropics Control Act regulates the import, export, manufacture, formulation of pharmaceutical preparations, transfer, and other handling of narcotics and psychotropics under the jurisdiction of MHLW. This law regulates the components and ingredients of narcotics but does not explicitly mention natural THC.

This legal framework has implications for how MHLW treats different hemp products during the import process. The report will explain these laws and their implications for export to Japan in detail.

# 2.2. Tariff Treatment

This report focuses on "Hemp extract – Cannabinoids" imported under Harmonized System (HS) Code 2907.29.

Product	HS Code	Note	Current U.S. Exports to Japan	Tariff for U.S. Goods
Hemp extract - Cannabinoids	2907.29	This is a broad HS Code that includes many other polyphenols in addition to CBD	Yes	3.1%

Imports of U.S. CBD products to Japan face a 3.1 percent tariff, unlike duty free entry for HS 2907.29 products from the Association of South East Asian Nations (ASEAN), Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), Generalized Scheme of Preferences, the European Union (EU), Switzerland and the United Kingdom (UK). China has

<sup>&</sup>lt;sup>1</sup> The Cannabis Control Act does not explicitly define "mature stalks." However, based on the judicial precedent, MHLW interprets "mature stalks" as "stalks of cannabis plants which have reached a state suitable for obtaining hemp as a textile product, have been separated from the cannabis plants, and have shapes suitable for it." Source: <u>https://www.fas.usda.gov/data/japan-japanese-import-regulations-industrial-hemp-products</u>

the same 3.1 percent tariff as the United States.

While HS 2907.29 is the HS Code used for hemp extracts in their pure form, many U.S. products containing cannabinoids or other hemp-derived products could potentially be in the form of packaged foods, cosmetics, beverages or pet products and would therefore use the HS code for the relevant packaged product. It is important for importers to confirm the correct HS Code with Japan Customs before export.

### 2.3. Japanese Domestic Hemp Production

Although hemp has a long history in Japan, primarily as fiber in textiles, ropes and paper, as well as food uses, modern domestic production is extremely small and mostly limited to traditional fiber production. For details, see the companion report titled *The Japanese Market for Hemp Fiber*. There is no domestic natural legal CBD production nor an expectation that a domestic natural CBD industry will develop in Japan in the foreseeable future.

# 3. CBD and Hemp Extracts

# 3.1. CBD Background

The market for imported CBD retail products, as well as bulk ingredients (isolate, distillate) is the main market in Japan for hemp derived products, and in the short-term, the market with the greatest potential for rapid expansion. CBD is not permitted to be sold as a medicinal product in Japan, but there has been special permission granted by the Japanese government for clinical trials of drugs that include CBD to treat epilepsy.

The importation of CBD is currently regulated as follows:

- Importation of CBD extracted from buds, leaves, flowers or any part of the cannabis plant that is not a mature stalk or seed is banned.
- Importation of CBD extracted from mature stalks and seeds is NOT prohibited as an ingredient for food, including nutraceuticals, cosmetics, vape liquid and pet food as long as THC is not detected.
- No contamination with THC is allowed. (There is zero-tolerance for THC and testing must show non-detected (ND).) Testing is required before export in the form of the Certificate of Analysis and CBD products may also be tested on arrival in Japan.

Industry sources generally do not view the zero tolerance for THC as a barrier for CBD imports as CBD manufacturers express confidence that they can manufacture CBD products with no detectable THC. However, the restriction on the eligible plant parts can be challenging for many U.S. manufacturers, who may make THC- free CBD from cannabis flowers, leaves and buds. Japan's restriction of eligible plant parts to mature stalks and seeds may prevent some U.S. manufacturers from entering the Japan market and also is reportedly one of the reasons many of the larger Japanese trading companies have not yet started to handle CBD products and bulk CBD ingredients, despite their interest.

In December 2017, the World Health Organization recommended that CBD not be "internationally scheduled as a controlled substance." Since 2018, when CBD began to enter the Japan market in earnest, MHLW began to become aware of the confusion the current Japanese legal framework was creating for CBD and initiated a working group in 2021 to discuss issues related to the Cannabis Control Act. As of November 2021, there has been no change in Japan's regulations pertaining to CBD products.

The strongly negative image in Japanese society of *taima*/cannabis, actively promoted by MHLW on its websites and in communication with the public<sup>2</sup>, makes any potential legal changes controversial. Many, if not most, Japanese consumers are unaware that CBD, despite its growing niche market, is extracted from the *taima*/cannabis plant. As more consumers realize that CBD comes from *taima*/cannabis, it is possible that there may be more consumer backlash

<sup>&</sup>lt;sup>2</sup> MHLW's website about cannabis (Japanese): <u>https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000193406.html</u>

about the use or sales of the products. Several importers mentioned that media attention in recent years on CBD importers whose products were detected to have THC and publicized on the MHLW website resulted in some increased negativity towards CBD as people began to associate CBD with THC and cannabis. Therefore, despite a huge potential market for U.S. CBD products in Japan, there is also a need for consumer education and the potential for public backlash and misunderstanding.

Nevertheless, interest in CBD from a variety of domestic industries has continued, as well as a growing interest from overseas suppliers.

# 3.2. CBD Market Size and Potential

According to industry contacts, it is estimated that there are now 120-150 companies, including very small ones, dealing with CBD products in Japan, either as importers, manufacturers, or distributors. While CBD is the main product in the Japanese cannabinoid market, other cannabinoids such as cannabigerol (CBG) and cannabinol (CBN) can be found in the market and are all treated the same under the import process.

The CBD import market can be divided into **two main categories: packaged retail-ready products and raw bulk CBD ingredients** (primarily isolate and distillate). Neither category has official trade data as there are no specific HS codes assigned to CBD-related products, and they are included in broader categories of packaged foods or polyphenols. Japan Customs confirmed that they do not track more detailed data for products in these categories.

#### **Retail Products**

In 2020, **the overall CBD food supplement market was already estimated to be a \$10-18 million market of retail-ready products**, both imported and made in Japan, with a 171 percent annual growth since 2019.<sup>3</sup> End uses were estimated to be 70 percent for food and 30 percent for cosmetics. Pet products were a small but growing share.

Industry contacts suggest that the CBD industry is now growing by about 200 percent annually and will continue at this rate for the foreseeable future. If imports of CBD extracted from the whole cannabis plant become legal in Japan, the market is expected to grow at an even more exponential rate; some importers are optimistic the Japan market could grow into a multibilliondollar market within the decade.

Currently retail-ready products are a larger share of the market than CBD raw materials. Some of these retail products are imported through standard channels, but many retail-ready products are imported as "personal imports" through direct online orders from U.S. e-commerce platforms or just brought in personal luggage for personal use.

Personal imports will not show up in trade statistics unless they have a declared value over

<sup>&</sup>lt;sup>3</sup> Data gathered from the Domestic Health and Beauty Market 2020 Survey (Fuji Keizai) and interviews with industry experts.

200,000 JPY (\$1,800) for online orders<sup>4</sup> and 300,000 JPY (\$2,700) for bringing in personal luggage<sup>5</sup>. Multi-level marketing (MLM) is one channel for CBD products and many MLM businesses reportedly import retail-ready products as personal imports.

#### Raw Bulk CBD Ingredients

- The majority is isolate (80 percent) and distillate (20 percent).
- The price of CBD isolate/distillate is currently reported to be around 1,000,000 JPY/kilograms (kg) (\$9,100). This high price is another reason why some major domestic Japanese manufacturers and traders have not entered the market yet.
- According to the industry, longer term, the bulk CBD market for supply to Japanese manufacturing is seen as a larger opportunity than retail-ready products from the United States.

Ever since MHLW published a document<sup>6</sup> with a detailed explanation on how to import CBD products into Japan and reconfirmed the zero tolerance for THC, Japanese buyers have become hesitant to handle even broad-spectrum CBD raw materials for fear of THC detection. For this reason, the Japanese market is primarily an isolate-based market. There are some limited imports of some broad-spectrum CBD ingredients, and some Japanese manufacturers use isolate and add terpenes for aroma and call it broad spectrum.

#### 3.2.1. CBD Products and Sales Channels

The number of CBD products available in the Japan market in the past year has shown a sharp increase. The main CBD products on the market are (listed roughly in the order of how frequently the product types were seen in retail, e-commerce during Meros' data collection):

- CBD oil and tinctures
- CBD gel capsules, gummies, beverages, CBD protein
- Liquid, wax, and cartridges for vape/e-tobacco
- CBD isolate powder
- CBD creams, bath bombs, shampoos and other cosmetics
- CBD oils and snacks for pets and animals

Judging from online sales rankings of major online shopping platforms such as Rakuten and Yahoo!, as well as interviews with CBD industry players, the first CBD products to be imported to Japan were CBD oils.

Within the past several years, vape products and gummies/supplements have followed. Cosmetics are still a smaller niche but considered a future "blue ocean" for CBD raw material suppliers.

Sellers report that women tend to be the majority of CBD customers as they tend to be the first adopters of new health products, while vape customers are more likely men.

<sup>&</sup>lt;sup>4</sup> Basic Notification on Statistics regarding Foreign Trade, etc. (Japanese): https://www.customs.go.jp/toukei/sankou/dgorder/TU-S59k1048.pdf

<sup>&</sup>lt;sup>5</sup> Basic Notification on Customs Law (Japanese):

https://www.customs.go.jp/kaisei/zeikantsutatsu/kihon/TU-S47k0100-s06-03~04.pdf

<sup>&</sup>lt;sup>6</sup> The original Japanese document is at <u>https://www.mhlw.go.jp/content/11120000/000638551.pdf</u> Please see the appendix for English translation.



CBD gummies (left), tinctures (middle) and pet oils and balms (right) are even more common than one year ago and seen in some mainstream chain stores. *Source: Meros Consulting* 

#### **CBD** sales channels in Japan

CBD products are niche products still found mostly through MLM businesses, online shops, specialty retailers and boutiques.

#### MLM businesses:

• U.S-based Morinda reportedly is the top player in the Japanese CBD supplement market; Kannaway is another growing U.S. MLM with Japan operations and focuses specifically on CBD products.

#### **Online sales channels:**

- Amazon, the largest online shopping platform in Japan, prohibits CBD products. They do sell some products marketed as "hemp oil" that are packaged and marketed similarly to CBD oils.
- The other two top online shopping platforms in Japan, Rakuten and Yahoo!, sell various CBD products.
- Mercari, the top consumer-to-consumer (C2C) shopping site, as well as many independent online shops, also sell CBD products.

#### Boutique stores focusing on health & "natural" products:

• Boutique chains including Aeon Body Shop, Shizenshokuhin F&F, and Biople by CosmeKitchen have CBD oil, gummies, cream and balm at their outlets; CBD specialty shops are also appearing.

#### **Retail chains:**

Most supermarkets and drug store chains have not yet started to sell CBD products, but there are already some examples:

- The major discount store chain Don Quijote has a large selection of gummies, oil and vapes.
- Major electronic retail chain Bic Camera sells some CBD vape liquid.
- Major drug store chain Welcia sells shampoo with citrus CBD (synthetic CBD<sup>7</sup> made from citrus peel).

<sup>&</sup>lt;sup>7</sup> Further explanation on synthetic CDB can be found in the next section.

#### Cafes and bars:

• A number of cafes and juice bars in most major Japanese cities offer CBD beverages and snacks.

#### **Clinics:**

CBD oil and nutraceuticals are sold at some medical clinics, and several associations promote CBD for clinics, e.g., <u>Clinical CBD Oil Study Group</u>

### 3.2.2. Synthetic CBD

**Synthetic CBD** is estimated to be about 2-3 percent of the CBD market. The Japanese industry felt that the natural and synthetic CBD were virtually interchangeable in terms of functionality. Interviewees expected that the synthetic market would grow in Japan if natural CBD imports remain limited due to the ban on CBD extracted from the whole cannabis plant.

However, as long as natural CBD is increasingly available and able to be imported smoothly, there is doubt that synthetic CBD would be a growing market in Japan. If further research and development show that synthetic CBD could be produced with more consistent quality or lower price over natural CBD, there may be end-channels that would display increased demand. At this time, industry experts report the current scale of global synthetic CBD production is not large enough to compete on price against natural CBD (which varies greatly in price and can be found quoted for \$1,500/kg to \$20,000/kg globally, with about \$10,000/kg a typically quoted price in Japan now.) Some industry experts in Japan estimated synthetic CBD at as much as \$15,000/kg now, but also with prices varying greatly. There is hope that as companies around the world try to produce synthetic CBD at greater scale, synthetic prices may decrease.

Synthetic CBD is not covered by the Cannabis Control Act, but importers do need to submit documents demonstrating that the product is not extracted/made from cannabis. The procedure is outlined in MHLW's "Pattern B" of MHLW's guide to CBD importation<sup>8</sup>.

There is at least one Japanese manufacturer who claims to make synthetic CBD from citrus peels for use in healthcare products.

#### 3.2.3. Other CBD Raw Materials and Competitors

**CBD retail-ready products** are currently imported from many countries including the United States, the EU, Australia, New Zealand and Canada. While some import relationships started from a commitment or relationship with a certain overseas brand or supplier, other buyers in Japan reported visiting factories in several countries to choose a supplier. Japanese buyers value quality control at factories and transparency in the manufacturing process.

Isolates: There is little difference perceived among suppliers of isolate in its pure forms. The

<sup>&</sup>lt;sup>8</sup> See Appendix for the MHLW memo that outlines the documents required for importing synthetic CBD products under their "Pattern B". Official document can be found here (Japanese): <u>https://www.ncd.mhlw.go.jp/dl\_data/cbd/guidecbd.pdf</u>

occasional complaint was that Chinese raw materials were sometimes inconsistent in their quality control or that Japanese consumers might feel a bias against Chinese-made ingredients. However, in the mid-term, China is expected to become a significant supplier of bulk CBD isolate and distillate for the Japanese manufacturing industry.

China has the same tariff as the U.S. on isolate (3.1 percent), but as bulk CBD as an ingredient becomes more mainstream, the 3.1 percent tariff on U.S. products could become a disadvantage for the U.S. against duty-free EU and CPTPP suppliers.

#### 3.2.4. Trends in Pet Foods With CBD

The pet food market in Japan is growing. According to the Japan Pet Food Association, the petfood market was valued at \$2.4 billion (270 billion JPY) in 2009 and increased to \$2.9 billion (319 billion JPY) in 2019. This steady growth in the pet industry in Japan makes importers of CBD products for pets, as well as domestic manufacturers of pet CBD products, very optimistic about market potential. Positive media articles about CBD for pets have increased, discussing CBD for improving pets' sleep, reducing stress, and preventing inflammation.

The pet CBD market in Japan reportedly started around 2019, slightly later than the 2018 breakthrough of CBD for human consumption. However, pet CBD products are still a very small share of the CBD product market and are likely to grow more slowly than CBD for human consumption. This is because CBD awareness itself is low in Japan and pet owners are unlikely to give something to their pet that they are not yet familiar with. According to the industry, there is a clear tendency in Japan for pet owners to choose supplements based on their own experience.

The CBD products for pets seen in the Japan market, in order of market share:

- 1. Oils, tinctures or capsules to be added to pet food or water
- 2. Pet snacks or treats (using CBD or hemp seed as an ingredient)
- 3. CBD creams for rubbing on pet skin

The main pet product is CBD oil and the main channel is veterinary hospitals. CBD products for pets are also found in e-commerce and in pet shops, but because most pet owners are unfamiliar with how to use them, it is more likely they will purchase after instructions on usage and dosage from a veterinarian. The pet products are both imported and domestically produced in Japan. To give a sense of the scale of domestic pet product production and distribution, one major CBD pet brand reported that they distribute to 60 veterinary hospitals – still a small distribution network. The products are marketed as supplements to add to pets' food or for use when pets are anxious or upset.

According to the industry, because there is still little scientific data and research about CBD effectiveness on pets, many Japanese veterinarians are not yet recommending CBD as a pet supplement.

Although CBD products for pets are promoted as being effective for pet pain, anxiety and stress, companies that sell CBD products also point out the need for caution when it comes to use in

animals due to this lack of empirical data.<sup>9</sup> The Animal CBD Research Society was established in 2018 to promote CBD in the veterinary field in Japan. Their activities include introducing the latest information, mainly from overseas, to its members (veterinarians and veterinary professionals) and to conduct studies on cannabinoids for pets in Japan.

<sup>&</sup>lt;sup>9</sup> <u>https://cbd.co.jp/column/pets-cbd/</u>, <u>https://takeuchi-md.jp/cbd/137</u>

# 4. Importing Products with CBD: Step-by-Step Guide

Below is a step-by-step check list for U.S. exporters of CBD products, including pet foods. The following pages will discuss the CBD-specific requirements in more detail, including the three key required documents. For further details on food import procedures, please consult the <u>FAS</u> <u>Import Regulations and Export Process</u> <u>Guides to Japan</u>, which include more information and examples of the required documents for foods and pet food products.

# Summary of Recommended Steps to export a CBD product to Japan (<u>Steps Highlighted in Red are Specific to CBD</u>)

#### A. Pre-Embarkation

- 1. Prepare an Ingredient List and a Manufacturing Process Flowchart (from extraction to packaging)
- □ 2. Confirm legal compliance with food standards, additives restrictions and other regulations
- □ 3. Check the tariff classification and customs duty with your importer
- □ 4. Create a product label for products destined for commercial sale
- **5**. Register trademarks and other intellectual property rights, if relevant

#### **B.** Embarkation

- □ 6. Obtain a Substance Analysis Report that conforms to MHLW requirements and confirms non-detection of THC
- □ 7. Obtain a written oath, signed by the Manufacturer, that declares the CBD in the product is from mature stalks or seeds.
- 8. Obtain photos of the stalks or seeds the CBD was made from and photos of the manufacturing process.
- 9. Clear export customs

#### **C. Import Clearance**

- □ 10. Have your importer submit the three required documents to MHLW and receive verbal confirmation that the product does not appear to contain any banned substances
- □ 11. Have your importer write a letter confirming this MHLW communication
- 12. Clear food safety quarantine procedures, if the CBD product is a food product
- 13. Importer or customs broker submits the letter on MHLW communication to Customs
- □ 14. Clear import customs



#### The Three Documents Required by MHLW for Prior Submission for all CBD Imports

To obtain verbal confirmation from MHLW that the CBD product appears to conform to Japanese regulation, MHLW recommends submitting the following documents to MHLW at least one month before the shipment is expected to clear Japan Customs, to ensure that all documents are reviewed, and any issues resolved. (See Appendix 1 for the full text of MHLW's memo on obtaining confirmation prior to importing CBD products)

# **1.** A letter from the manufacturer of the CBD product that declares that the CBD contained in the products is made from mature stems and seeds, including:

- Statement that the CBD contained in the product to be imported is extracted and manufactured from mature stem and/or seed of cannabis plants;
- Date of documentation;
- Name, title and signature of the person responsible for manufacturing

# **2.** A Substance Analysis Report of CBD products to be imported that certifies the results of laboratory testing in the country of origin, including:

- Results of THC and CBD analysis conducted before embarkation
- Date of the analysis conducted or date of the report created;
- Product numbers or lot numbers of the products (in order to prove that this analysis report analyzes the same products that are going to be imported);
- Name, title and signature of the person who is responsible for the laboratory or of the person who performed the analysis;
- Analysis methodology and Limit of Detection (LOD).

#### 3. Photos of raw materials and manufacturing process

Photos of the raw materials used to manufacture the CBD – must show the whole stalk end-to-end, not a photo of some part of a stalk. Photos of manufacturing process that show clearly that the raw materials declared in the above letter are used for manufacturing and comply with MHLW's requirement that the manufacturing process does not use buds, leaves or any other part of the cannabis plant except stalks or seeds.

Note that CBD products for human consumption, such as oil to be consumed by mouth, gummies or tinctures are considered food items and are subject to the Food Sanitation Act. These CBD products must pass quarantine clearance as a food item, a process handled by the importer. CBD products that are not sold as food, such as balms, vape products, cosmetics and pet products do not require quarantine clearance for sale as food. Note that melatonin is not legal to import or sell in Japan. Therefore, U.S. CBD gummies with melatonin cannot be exported to Japan.

Exporters must obtain a Substance Analysis Report that includes all points required by MHLW as outlined above. MHLW does not have any specific laboratories approved in the United

States for testing of CBD products.<sup>10</sup> As part of the customs clearance procedures for CBD products, the importer must get verbal confirmation from MHLW that, based on the information provided by the importer, the CBD product does not seem to fall into any prohibited category.

- This requirement for verbal confirmation is not explicitly written in the Customs Law but is in a memo released by MHLW (see Appendix 1).
- Due to a huge growth in CBD exports, some CBD importers are currently reporting very long wait times at Customs (several weeks after the submission of the completed documents for the approval process).
- Japan Customs will not test every shipment of CBD products for THC, but importers should be aware that testing is possible during the import process.
- Changes in the process regarding CBD imports are not always immediately publicized by MHLW, so close communication with the Japanese importer is recommended.

# What happens to an importer whose shipment of CBD products is rejected because of THC detection?

If a shipment of CBD product is rejected because of THC detection, the shipment is destroyed. It cannot be returned to the country of origin or rerouted to another destination as Article 4 of the Cannabis Control Act forbids export of cannabis, and the presence of THC will categorize the shipment as cannabis. As long as Customs does not feel there was any deception (i.e., U.S. tests showed undetectable THC, but the Japanese tests showed THC), there is no penalty to the importer nor the exporter. The importer can try again with another shipment.

On the other hand, if CBD products that have already been imported and distributed in Japan are found to contain THC, the importer's name and product name will be disclosed on the MHLW website and the products will be recalled<sup>11</sup>.

Overall, importers report that Customs check ALL documents (labels, ingredient lists, etc.) of products containing CBD more carefully than other food products.

<sup>10</sup> MHLW maintains a list of registered U.S. labs providing Certificates of Analysis for testing food for other substances such as restricted food additives or agrochemical residue. List is found at <a href="https://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf">https://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf</a>

<sup>&</sup>lt;sup>11</sup> <u>https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\_iryou/iyakuhin/yakubuturanyou/other/torishimari\_00004.html</u> <u>https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\_iryou/iyakuhin/yakubuturanyou/other/torishimari\_00001.html</u>

# 5. Appendix 1: Procedure for Obtaining MHLW Confirmation on CBD Products

The process for obtaining MHLW confirmation for import of CBD products is found in a 2020 guidance memo on MHLW's Information on Drug Abuse Prevention webpage.<sup>12</sup> This is Meros' translation of the document as posted on the MHLW website as of October 2021.

For those who are considering importing CBD (\*) oil and other CBD products (\*) CBD refers to Cannabidiol.

Important to Read

- The Ministry of Health, Labour and Welfare (MHLW) 's confirmation of whether or not a product falls under the category of "cannabis" based on this guide is based on the materials submitted by the importer. MHLW's confirmation does not determine whether what you are actually trying to import is 'cannabis'. Please note that materials submitted to MHLW may need to be submitted again to Customs or MHLW when actually importing.
   Therefore, even if MHLW confirms that a product is "not considered cannabis" based on the materials submitted, if THC is detected during an inspection by Customs or MHLW at the time of importation, or in a domestic inspection, etc., you may be punished under the Cannabis Control Act as having imported something "considered cannabis".
- Since the export of "cannabis" is prohibited, if THC is detected in a test, etc., the products cannot be returned to the exporting country.

#### (Process)

- This process should be conducted by the importer.
- We can only accept requests by e-mail. Please include the importer's name (or company name and name of the person in charge if the importer is a company) and contact telephone number in the body of the e-mail. Please attach a set of the documents listed in section 3 below and submit them to the e-mail address in the "Inquiries" section. Note that we may not be able to receive large email attachments. For large attachments, please compress them in a .zip file and send in several separate emails.
- As soon as we confirm, we will call the number provided in the email.

<sup>&</sup>lt;sup>12</sup> The original Japanese document is here: <u>https://www.mhlw.go.jp/content/11120000/000638551.pdf</u> The document is found on the MHLW's Information on Drug Abuse Prevention webpage: <u>https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\_iryou/iyakuhin/yakubuturanyou/index.html</u>

#### 1. Regarding the regulation of cannabis

- (1) What is "cannabis" under the Cannabis Control Act?
- "Cannabis" means the cannabis plant (*Cannabis sativa* L.) and its products.
- However, the grown stalk of the cannabis plant and products such as fibers made from such stems (excluding resins) and seeds of the cannabis plant and their products are exempt from regulation.
- In Japan, only cannabis handlers (cannabis cultivators and cannabis researchers) licensed by the prefectural government are allowed to cultivate, possess, transfer, accept, etc., cannabis, and anyone other than cannabis handlers will be punished if they do so.
- Importing cannabis can only be done by cannabis researchers for research purposes and with the permission of the Minister of Health, Labour and Welfare.
- (2) Prohibited acts
- The import, export, cultivation, possession, transfer, acceptance, etc. of cannabis is prohibited.
- There are severe penalties for violators.

Conditio ns	Penalti es	
Cultivation/Import/Export	For personal use: imprisonment for up to 7 years (for profit: imprisonment for up to 10 years $+a$ fine of up to 3 million yen <sup>13</sup> )	
Possession/Transfer/Acceptance	For personal use: imprisonment for up to 5 years (for profit: imprisonment for up to 7 years $+a$ fine of up to 2 million years	

#### 2. About CBD products

- CBD products extracted and manufactured from parts other than the mature stems or seeds of cannabis plant (leaves, buds, branches, roots, etc.) are considered to be "cannabis".
- CBD products that contain tetrahydrocannabinol (THC), whether or not extracted or manufactured from cannabis plant, cannot be imported as a general rule because it cannot be confirmed that they do not fall under the category of "cannabis". In addition, chemically synthesized THC is regulated as a "narcotic" under the Narcotics and Psychotropics Control Act and therefore cannot be imported in principle.

\* Importation of "cannabis" is only possible if the cannabis researcher has received permission from the Minister of Health, Labour and Welfare.

<sup>&</sup>lt;sup>13</sup> 3 million yen (about \$27,000 USD)

<sup>&</sup>lt;sup>14</sup> 2 million yen (about \$18,000 USD)

The importation of "narcotics" is possible only when the drug importer is licensed by the Minister of Health, Labour and Welfare.

- Anyone who imports, exports, possesses, transfers, accepts CBD products that fall under the category of "cannabis" may be penalized.
- Although chemically synthesized CBD is not subject to regulation, you may be asked to confirm that it is not "cannabis" before importing it.

## 3. Importing CBD products

- When importing CBD products, please submit the following materials to [see Inquiries] in advance for each import (For the email address to which the materials should be sent, please refer to [Inquiries] above).
- We will determine whether or not the CBD product falls under the "cannabis" category under the Cannabis Control Act, based on the materials submitted to us prior to importation.

#### Pattern A

#### [In the case that the CBD product you are trying to import is made from cannabis plant]

<Required Documents>

All documentation must be obtained from the manufacturer of the CBD product. Documents can be in any format.

Please email the documents in the form they were obtained from the manufacturer. Please include the following information in the body of the e-mail

- The name of the importer (if the importer is a company, the name of the company and the name of the person in charge)
- Contact telephone number of the importer

#### 1 Certificate

A document that says "the CBD product is extracted and manufactured from the mature stems or seeds of cannabis plant"

The certificate must include the following information.

- Date of documentation
- The signature and title of the person responsible for manufacturing
- Statement that the CBD contained in the product to be imported is extracted or manufactured from the mature stems or seeds of cannabis plant

#### 2 Substance Analysis Report

Analyses showing the test results of the CBD product you intend to import

The following information must be included in the ingredient analysis form.

- Results of THC and CBD analysis
- Date of the analysis conducted or date of documentation
- Product numbers or lot numbers that identify the products to be imported
- The signature and title of the person who is responsible for the laboratory or of the person who performed the analysis
- Analysis methodology and Limit of Detection (LOD)

#### 3 Photo

Photos of the CBD's raw materials and manufacturing process

<Raw Materials>

- A photo is required to prove that only mature stems or seeds of cannabis plant are used as raw materials for the CBD (no leaves, buds, branches, roots, etc. of cannabis plant are used).
- A photo of just one part of the raw material is not sufficient to confirm that there are no roots, branches, etc., so it is necessary to have a photo that shows the whole raw material, end-to-end.

<Manufacturing Process>

- One example is a photo of mature stems, etc. of cannabis plant in a machine or a photo of the extraction from mature stems, etc. of cannabis plant.
- This is to confirm that nothing other than mature stems or seeds of cannabis plant are used as raw materials for CBD, not limited to plant parts mentioned above.

If the photos of the raw materials and manufacturing process are not clear, we may not be able to issue a confirmation.

#### Pattern B

#### [In the case that the CBD product you are trying to import is not made from cannabis plant]

<Necessary documents>

Documentation must be obtained from the manufacturer, etc. of the CBD product. Documents can be in any format.

Please send the documents obtained from the manufacturer, etc. by email

#### 1 Certificate

Documentation to prove that the CBD product was manufactured using chemically synthesized CBD

The certificate must include the following information.

- Chemical substances used as raw materials
- Synthesis method
- Date of documentation
- The signature and title of the person responsible for manufacturing
- Statement that the CBD contained in the product to be imported was obtained by chemical synthesis

#### 2 Substance Analysis Report

Analyses showing the test results of the CBD product you intend to import

The following information must be included in the ingredient analysis form.

- Results of THC and CBD analysis
- Date of the analysis conducted or date of the report created
- Product numbers or lot numbers that identify the products to be imported
- The signature and title of the person who is responsible for the laboratory or of the person who performed the analysis
- Analysis methodology and Limit of Detection (LOD)

<Other required information when submitting documents>

Name of the importer (company name)

Contact phone number

# 4. To those who have received a "Notice of Customs Procedures for Mail Arriving from Abroad"

Since there is a possibility that the package contents may fall under the category of cannabis under the Cannabis Control Law, please email us the following information in addition to the information required in 3.

- The name of the customs office where the mail is kept and its contact information
- Notification number
- The importer's name (if the importer is a company, the company name and the name of the person in charge)
- Contact telephone number of the importer

# 6. Appendix 2: Laws and Regulations relevant to Import of CBD products

Below are the importation laws and regulations relevant to CBD by type of product. This appendix will explain each of these laws and their significance for CBD product exporters.

Type of product	Relevant laws and regulations			
Laws & regulations which relate to all CBD products				
A. All CBD products	<ul> <li>The Customs Act</li> <li>The Cannabis Control Act</li> <li>The Narcotics and Psychotropics Control Act</li> </ul>			
Additional laws that are relevant depending on the CBD product				
B. CBD for food ingredients and CBD food products	<ul> <li>The Food Sanitation Act</li> <li>The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices</li> </ul>			
C. CBD vape/e-tobacco liquid & products	<ul> <li>The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices</li> </ul>			
D. CBD for cosmetics ingredients and CBD cosmetic products	<ul> <li>The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices</li> </ul>			
E. CBD for pet food ingredients and CBD pet food products	• The Act on Ensuring the Safety of Pet Food			

### 6.1. The Customs Act

The Customs Act covers the Customs procedures for the exportation and importation of all goods into Japan. This Act requires that anyone wishing to import goods into Japan must declare them to the Director-General of Japan Customs and then obtain an import permit after necessary examination of the goods.

The Act bans importation of "cannabis" and "narcotics" under Article 69-11 (i). The word "cannabis" is not defined in the Customs Act but it is in effect following the definition laid out in the Cannabis Control Act. The word "narcotics" follows the definition laid out in the Narcotics and Psychotropics Control Act.

In practice, as part of the customs clearance procedures for CBD products, the importer must get verbal confirmation from MHLW that, based on the information provided by the importer, the CBD product does not seem to fall into any prohibited category.

This requirement for verbal confirmation is not explicitly written in the Customs Law. However, this process was outlined in a memo released by MHLW. A translation of this memo is included in Appendix 1.<sup>15</sup>

#### The Acts & Regulations are available at:

The Customs Act (Act No. 61 of 1954)

- In Japanese, the link below is the Mar 31, 2020 version (reflecting the latest revision) <u>https://elaws.e-</u> gov.go.jp/search/elawsSearch/elaws\_search/lsg0500/detail?lawId=329AC000000061\_20191216 \_501AC0000000016&openerCode=1#AB
- In English, the link below is the Mar 31, 2020 version (reflecting the latest revision), translated by Japan Tariff Association <u>https://www.kanzei.or.jp/kanzei\_law/329AC000000061.en.html</u>

#### **Responsible government agencies**

Japan Customs, Japanese Ministry of Finance <u>https://www.customs.go.jp/</u> (Japanese)

Contact details for the nine regional Customs offices are available at: <u>http://www.customs.go.jp/question\_e.htm</u> (English)

<sup>&</sup>lt;sup>15</sup> The original Japanese document is here: <u>https://www.mhlw.go.jp/content/11120000/000638551.pdf</u> The document is found on the MHLW's Information on Drug Abuse Prevention webpage: <u>https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\_iryou/iyakuhin/yakubuturanyou/index.html</u>

### 6.2. The Cannabis Control Act

The Cannabis Control Act was written in 1948 and regulates cannabis, including possession, cultivation and exchange under the jurisdiction of MHLW.

The Act prohibits any person from importing 'cannabis', with the exception of cases where a cannabis researcher receives authorization from MHLW [Article 4 (i)].

The significance of this Act for CBD exporters is that as long as CBD is made from mature stalks and seeds, then the product is not regulated as cannabis under Japanese law and may be imported.

#### The Cannabis Control Act is available here:

The original Japanese of the June 2019 version (the most recent enacted version as of November 29, 2021) can be found at: <u>https://elaws.e-gov.go.jp/document?lawid=323AC000000124</u>

A line-by-line Japanese and English translation reflecting the December 1999 version can be found at the link below. There have been no changes to the definition of "cannabis" between the 1999 and 2019 versions. http://www.japaneselawtranslation.go.jp/law/detail/?id=2594&vm=&re

A downloadable PDF of the Ministry of Justice's (unofficial) English translation of the 1999 version of the Act can be found here:

#### **Responsible government agencies**

Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW) Phone: +81-3-3595-2436

Narcotics Control Department, Kanto-Shinetsu Regional Bureau of Health and Welfare, <u>https://kouseikyoku.mhlw.go.jp/kantoshinetsu/gyomu/bu\_ka/mayaku\_torishimari/index.html</u> (Japanese) Phone: +81-3-3512-8688 (Japanese only)

Email: <u>CHECKCBD@mhlw.go.jp</u> (Japanese only)

## 6.3. The Narcotics and Psychotropics Control Act

The Narcotics and Psychotropics Control Act regulates the import, export, manufacture, formulation of pharmaceutical preparations, transfer, and other handling of narcotics and psychotropics under the jurisdiction of MHLW.

The Act defines 'narcotics' to include the substances prescribed by the Cabinet Order under "Article 2 (i) and Appended Table I". The Cabinet Order of Specifying Narcotics, Plants Containing a Narcotic Raw Material, Psychotropics and Raw Materials of Narcotics and Psychotropics includes **chemically synthesized** Delta-8 THC, chemically synthesized Delta-9 THC, as well as Delta-10 THC, Delta-7 THC, Delta-6a (10a) THC, and Delta-6a (7) THC under Article 1 (lxxiv)-(lxix) of the Cabinet Order. The Act prohibits anyone from importing a 'narcotic', unless they have special permission, such as medical researchers or those requiring it for treatment of an illness.

According to MHLW, natural THC originating from cannabis plants is banned under the Cannabis Control Act and chemically synthesized THC is banned under the Narcotics and Psychotropics Control Act. Exporters should be aware that all THC is banned in Japan.

#### The Acts & Regulations are available at:

#### The Narcotics and Psychotropics Control Act (Act No. 14 of 1953)

The link below is the Dec 4, 2019 version in Japanese (reflecting the latest revision) https://elaws.e-gov.go.jp/search/elawsSearch/lsg0500/detail?lawId=328AC0000000014

For English, the link below is the Jun 26, 2015 version (the June 14 and December 4, 2019 revisions made no changes related to articles relevant to CBD): the Ministry of Justice's unofficial translation http://www.japaneselawtranslation.go.jp/law/detail/?id=2849&vm=04re=02

# Cabinet Order of Specifying Narcotics, Plants Containing a Narcotic Raw Material, Psychotropics and Raw Materials of Narcotics and Psychotropics (Cabinet Order No. 238 of 1990)

In Japanese, the link below is the July 8, 2020 version (reflecting the latest revision)

https://elaws.e-gov.go.jp/search/elawsSearch/elaws\_search/lsg0500/detail?lawId=402CO000000238

# 6.4. The Food Sanitation Act

CBD exports that are in the form of food products (gummies, cookies, beverages, etc.) or are for use as a food ingredient are subject to the Food Sanitation Act. The Food Sanitation Act outlines the necessary regulations related to food imports from a perspective of public health under the jurisdiction of the MHLW and the Consumer Affairs Agency (CAA). This Act defines the term 'food' as all food and drink except pharmaceutical or quasi-pharmaceutical products. These are defined by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices [Article 4]

Based on this Act, anyone exporting CBD products as a food product or a food ingredient must have their importer declare the products to a quarantine station under MHLW and obtain an import permit after a required examination. The Act establishes the sanitary standards for food products and the importer has to adhere to these standards.

Some of the common challenges related to the Japanese food sanitation standards for imported foods include:

- **Food additive** regulations are very strict. As of January 2021, Japan had approved only 829 additives (including fragrances and excluding natural flavorings).
- Agrochemical residues can be a problematic issue, due to occasional differences in the level of tolerance between the United States and Japan. Japan has not set any product-specific maximum residue limits (MRL) for cannabis. However, substances without a set limit are subject to the default MRL of 0.01 parts per million (ppm).
- Medicinal substances: Relevant for CBD products is that melatonin is not legal to import or sell in Japan. Therefore, U.S. CBD gummies with melatonin are not legal in Japan. This regulation has caused trouble for U.S. exporters in the past.

The CBD importers feel hemp-derived products face increased scrutiny in terms of all customs documents and food safety requirements and therefore it is best for U.S. exporters to be particularly careful that all documents are thorough and complete.

#### The Acts & Regulations are available at:

#### The Food Sanitation Act (Act No. 233 of 1947)

For Japanese, the link below is the Jun 15, 2018 version (reflecting the latest revision) https://elaws.e-gov.go.jp/search/elawsSearch/elaws\_search/lsg0500/detail?lawId=322AC000000233

For English, this is the link to the Ministry of Justice's unofficial English translation of the June 7, 2006 version <u>http://www.japaneselawtranslation.go.jp/law/detail/?id=12&vm=04&re=01</u>

### 6.5. The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals & Medical Devices

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices sets rules for products such as medicinal products, medical devices and cosmetic products in Japan under the jurisdiction of MHLW.

While import regulations for CBD cosmetics and vape liquids are outside the scope of this report, imported CBD raw materials are used for domestic manufacturing of cosmetics and vape products.

This act is relevant for CBD exports in several potential ways:

- For CBD for use in cosmetic products
- For potential exporters of e-vape/vape liquid containing CBD
- CBD products for pets

#### Cosmetics

While CBD in cosmetics is still a small share of the market, this is considered a future growing opportunity for U.S. suppliers of CBD retail cosmetics and also of bulk isolate, distillate and other forms of CBD extracts for the Japanese cosmetics industry.

This act defines the term 'cosmetic' as items which are intended to be used on the human body by rubbing, sprinkling or other similar means, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition, and which have mild effects on the human body. Based on the act, MHLW set the <u>Standards of Cosmetics</u>.

In order to import and sell cosmetics (including bulk ingredients) in Japan, an importer needs to get a license from the Pharmaceutical Affairs Division of the prefecture where import port of entry is located, according to this Act. The products must meet the Standards of Cosmetics.

There are no specific regulations or standards for CBD in cosmetic products; thus, the importer should follow the general rules for importing cosmetics. There are also currently no specific regulations for importation of CBD as a cosmetics ingredient so general regulations for importing CBD products should be followed.

#### E-Vape/Vape Liquid

Under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, liquid for vape/e-tobacco contained nicotine is considered to be a medical product. Therefore, vape/e-tobacco liquid containing nicotine cannot be imported to Japan unless both the importer and the manufacturer of liquid containing nicotine obtain permission from MHLW for each product. According to a phone interview with the MHLW on June 9, 2021, MHLW has never issued any permits for liquid containing nicotine, so an import of vape/e-tobacco liquid containing nicotine is practically not possible.

However, vape/e-tobacco liquid without nicotine can be imported to Japan. There are no specific regulations for importation of CBD vape liquid which does not contain nicotine. As

long as CBD vape liquid does not contain nicotine, it can be imported under the standard CBD import process.

#### **CBD** Products Claiming Medicinal Benefits or Containing Medicinal Components

Depending on the ingredients/components of a CBD product or what kind of efficacy is being claimed for the product, the product may be subject to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. If there is any doubt, the Pharmaceutical Affairs Division of each prefectural government will help importers to determine whether their products are subject to this Act. If the Pharmaceutical Affairs Division of the prefecture you plan to import into confirms that the product is subject to the Act, the importer and U.S. manufacturer will need to get approval for the product from MHLW.

#### **CBD Products for Pets**

Veterinary medicines, quasi-drugs for animals and veterinary medical devices are also regulated under the Act on Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices and Other Products. The criteria for determining whether a product is a veterinary medicinal product are set out in the "Criteria for the Scope of Veterinary Medicinal Products" (Notification of the Director-General of the Consumer Affairs and Safety Bureau, Ministry of Agriculture, Forestry and Fisheries, No. 26-4121, November 25, 2014). Currently, CBD in pet food is categorized as a food ingredient, and not as a pharmaceutical ingredient.

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) is available here:

For Japanese, the December 4, 2019 version is the latest revision: <u>https://elaws.e-gov.go.jp</u>

/search/elawsSearch/elaws\_search/lsg0500/detail?lawId=335AC0000000145

For English, the link here is to Ministry of Justice's unofficial translation of the June 26, 2015 version (December 16, 2016, June 16, 2017, July 6, 2018, June 14 and December 4, 2019 revisions made no changes to articles relevant to CBD. <u>http://www.japaneselawtranslation.go.jp/law/detail/?id=3213&vm=04&re=01</u>

Responsible government agencies

Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW) Phone: +81-3-3595-2436

Contacts of Pharmaceutical Affairs Division of each prefectural government are available at: <u>https://www.yakujihou.com/co/link.html (Japanese)</u>

## 6.6. The Act on Ensuring the Safety of Pet Food

#### Pet food for Cats and Dogs

The Act on Ensuring the Safety of Pet Food establishes the standards for pet food products for cats and dogs under the jurisdiction of the Ministry of Agriculture, Forestry and Fisheries (MAFF) and Ministry of the Environment. This Act defines the term 'pet food' as that which is used for the purpose of providing nutrition to pets (cats and dogs), excluding veterinary medicine.

There are no specific regulations or standards for CBD in pet food products. CBD snacks and treats for pets are considered "pet food" under Japanese law. Therefore, exporters should follow the general rules for pet food imports, in addition to the rules for importing products including CBD.

Note that veterinary medicines are covered by The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. CBD is not approved as a veterinary medicine. Items such as pet supplements may be classified as medicinal products depending on the ingredients and efficacy claims. If in doubt, importers should consult MAFF.

#### Pet food and pet food ingredients for animals other than cats and dogs

No specific regulations apply to importation of CBD as an animal food and animal food ingredient. These products must follow the standard CBD import process.

#### **The Acts & Regulations are available at:**

#### The Act on Ensuring the Safety of Pet Food (Act No. 83 of 2008)

For Japanese

https://elaws.egov.go.jp/search/elawsSearch/elaws\_search/lsg0500/detail?lawId=420AC000000083

For English, the Food and Agricultural Materials Inspection Center's (FAMIC) unofficial translation

http://www.famic.go.jp/ffis/pet/obj/sub1e\_houritu.pdf

The Ministerial Ordinance on Standards of Pet Food (Ordinance of the Ministry of Agriculture, Forestry and Fisheries and the Ministry of the Environment No. 1 of 2009)

For Japanese, the link below is the April 1, 2021 version (reflecting the latest revision)

https://elaws.e-gov.go.jp/document?lawid=421M60001200001\_20211001\_503M60001200002

For English, the link below is the April 1, 2021 version (reflecting the latest revision) of FAMIC's unofficial translation.

http://www.famic.go.jp/ffis/pet/obj/sub1e\_seibunkikaku.pdf

■ Responsible government agencies

Regional Agricultural Administrations under MAFF are the contact point for importers. Contact phone numbers are available at: <u>http://www.maff.go.jp/j/syouan/tikusui/petfood/</u> (Japanese)

### Attachments:

No Attachments.