

**Voluntary Report** – Voluntary - Public Distribution

**Date:** August 09, 2023

**Report Number:** JA2023-0066

**Report Name:** The Japanese Market for Hemp Seed and Hemp Seed Oil Products

**Country:** Japan

**Post:** Tokyo

**Report Category:** Agricultural Situation, Exporter Guide, MISC-Commodity, Sanitary/Phytosanitary/Food Safety

**Prepared By:** Tomohiro Kurai

**Approved By:** Mariya Rakhovskaya

**Report Highlights:**

The aim of this report is to inform potential U.S. exporters of hemp seed and hemp seed oil products about relevant import regulations and market opportunities in Japan. It is a rapidly evolving market and changes in regulations, laws and requirements can be expected for various hemp-derived products in the next several years.

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# 1. Introduction

The aim of this report is to inform potential U.S. exporters of hemp seed and hemp seed oil 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 hemp product market. It is a rapidly evolving market and changes in regulations, laws and requirements can be expected for various hemp-derived products in the next several years.

For information on Japanese regulations for cannabidiol (CBD) and hemp fiber products, please see *The Japanese Market for Hemp Fiber* and *The Japan Market for CBD and Hemp Extracts* respectively. For further details on import regulations and export processes for exporting food products to Japan, please refer to [FAS's Import Regulations and Export Guides to Japan](#), which offer 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](mailto:AgTokyo@fas.usda.gov)

## Terms Used

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 specifically to the *Cannabis sativa L* plant. The word **hemp** is used 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.

See the Glossary on the next page for more information.

## Glossary

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

	Definition
Cannabis	Cannabis refers to the plant <i>Cannabis sativa L.</i>
Hemp	Hemp refers to the parts of the cannabis plant that may be legally marketed and imported to Japan, specifically mature stalks (excluding resin) and seeds of the plant and their products.
Hemp seed oil	Oil extracted from cannabis seeds.
Cannabinoids	Naturally occurring compounds found in cannabis. There are several hundred compounds found in the cannabis plant and at least 100 are classified as cannabinoids, each with different effects. Some of these include THC, CBD and CBG.
THC (Tetrahydrocannabinol)	The principal psychoactive constituent of cannabis.
CBD (Cannabidiol)	A cannabinoid used in products such as oils and edibles
Hemp oilcake/meal	By-product after oil extraction from hemp seeds. Commonly used as animal feed, but also can have application in food products, such as dairy alternatives.

## 2. General Background

### 2.1. Legal Framework and Tariff Treatment

Under Japan’s regulatory framework, The Cannabis Control Act bans importation of cannabis. However, mature or “grown” cannabis stalks<sup>1</sup> and products made from stalks (excluding resin), as well as cannabis seeds and products made from the seeds are not included in the definition of “cannabis”.

Japan has zero tolerance policy for tetrahydrocannabinol (THC). Although the Cannabis Control Act does not explicitly mention THC, in practice, the Ministry of Health, Labour and Welfare (MHLW) interprets the presence of THC in a product to mean that parts of the cannabis plant other than the mature stalks and seeds were used. Unacceptable parts include flowers, buds, leaves, immature stalks, or roots. A cannabis-derived product 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.

This legal situation has implications for how MHLW treats different hemp-derived products during the import process. The report will explain these laws and their implications specifically for export of hemp seed and hemp seed oil products to Japan.

Hemp seed, hemp seed oil and byproducts like hemp seed cake fall under different Harmonized System (HS) Codes as seen below. Japan does not impose tariffs on hemp oil and hemp seed products imported under these codes.

Product	HS Code	Note	Current U.S. Exports to Japan	Tariff for U.S. Goods
Hempseed	1207.99.010	Japan has an HS Code specifically for hemp seed	No	None
Hemp Oil	1515.90.510	Broad oil category (Of an acid value exceeding 0.6)	Yes	None
	1515.90.520	Broad oil category (Of an acid value less than 0.6)		None
Hempseed Cake/Meal	2306.90.090	This is a broad HS Code that includes many other oilcakes	No	None

The HS codes above represent hemp products in their pure form. U.S. products containing hemp seed or other hemp-derived products could potentially be in the form of packaged foods, nutritional supplements (e.g. soft gel capsules, hemp gummies), beverages or pet products and

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<sup>1</sup> The Cannabis Control Act does not explicitly define “mature” or “grown” stalks. However, based on 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: <https://www.fas.usda.gov/data/japan-japanese-import-regulations-industrial-hemp-products>

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.**

## **2.2. Japanese Domestic Production of Hemp**

Hemp production has a long history in Japan, primarily for use in textiles, ropes, industrial and food uses, but the modern Japanese domestic hemp market is extremely small. Domestically produced hemp has very limited usage, principally as fiber for rituals connected to the Shinto religion. Although traditionally hemp seeds were consumed in Japan, today, domestic hemp seeds are almost never used for food, due to both the strict regulation of domestic cultivation of the cannabis plant, as well as the cheaper hemp seed imports readily available.

There is some interest in the revival of the domestic hemp industry for food use among some associations, but these efforts are still extremely limited. According to the industry, for Japan to expand its hemp industry, it would require both a revision of laws concerning cannabis cultivation licensing, as well as technical education on modern cultivation and uses of hemp.

At least one domestic hemp food producer has received permission from Tochigi Prefecture, the main area of licensed cannabis cultivation, to create a food-grade hemp charcoal product from domestic hemp stalks. This product is available online and marketed as a health food but is a limited and experimental product.

Overall, there is no expectation that a domestic Japanese hemp seed or hemp seed oil industry will be developed in the foreseeable future.

For further details about domestic cannabis production, please refer to *The Japan Market for Hemp Fiber*.

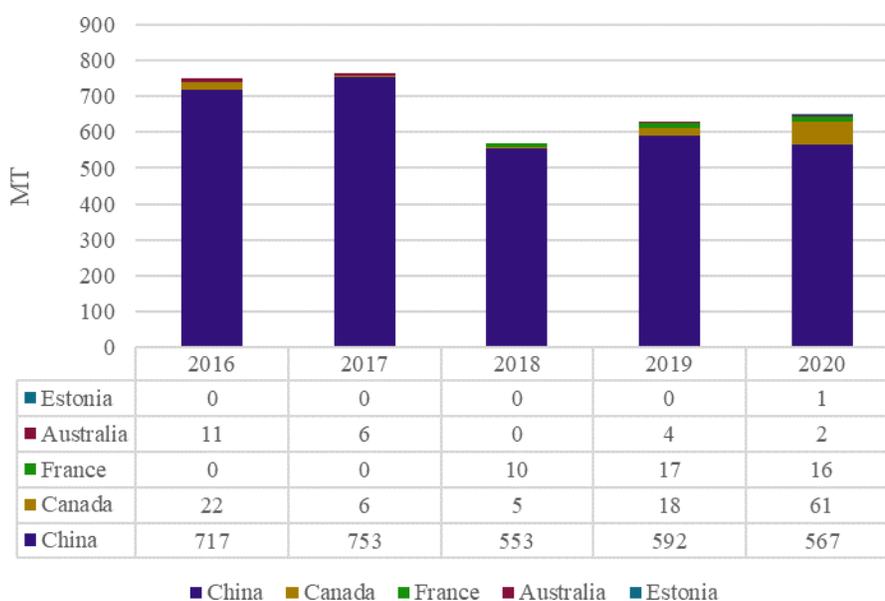
### 3. Hemp Seed Market

In 2020, Japan imported about 650 metric tons (MT) of hemp seed, with China as the main supplier. It is estimated that the 80 percent of the hemp seed market is for bird feed and 20 percent is for human food, but that most of the recent increase is for human use, including the recent increase in non-Chinese suppliers. The bird feed market has remained largely stagnant at approximately 520 MT.

According to industry contacts, about 20 companies supply the hemp seed market and no more than 40-50 companies in Japan handle hemp seed for human use in some form. Costco has sometimes sold hemp seed for human use and was estimated to likely be the historically largest seller by volume.

Hemp seed for human consumption and for feed share the same HS Code 1207.99.010.

#### Hemp Seed Imports to Japan 2016-2020 (HS 1207.99.010)



Source: International Trade Center Statistics (ITC)

#### 3.1. Hemp Seed Products and Trends

Until fairly recently, the main use of domestic hemp seed for humans was the hemp seed (in the shell) that is traditionally found in the common Japanese *shichimi*, “seven spice powder”. Today all *shichimi* brands use hemp seeds from China, not domestic sources. One major *shichimi* manufacturer who advertises an “all Japanese *shichimi*” does not use hemp seeds.

Hemp seed for human use enjoyed a modest bump in sales as a “superfood” between 2018 and 2020, along with chia seed and flax seed, but the superfood buzz for hemp seed appears to be fading. A stronger driver now appears to be the efforts of several product manufacturers who are actively promoting their products. These one or two pioneering hemp seed product manufacturers are putting in the promotion and marketing needed to push the category and their own businesses have grown exponentially, from a small base. Hemp seed can be found in health food stores and online, marketed as a healthy addition to smoothies or food recipes, rich with omega-3. Shelled hemp seed is marketed as hemp nuts or hemp hearts. There are also products such as hemp protein (ground hemp seed), hemp milk and health bars including hemp seed.

According to trade statistics, hemp seeds imports from Europe and Canada are starting to grow. EU growth is reportedly in part because of aggressive sales efforts from the EU suppliers who invite Japanese buyers to their farms and facilities. However, industry contacts indicate that U.S. and Canadian hemp seeds remain of interest as well. Fundamentally, quality control from farm to factory is the deciding factor in choosing hemp seed suppliers for human food products.

Hemp seed is not expected to grow at explosive rates like the CBD market and prices are still relatively high for people to consider hemp seed as a daily product for adding to yogurts or smoothies. However, there is optimism in the industry that the overall buzz around hemp and CBD products worldwide will drive increased growth in the health food sector for hemp seeds and hemp seed-derived products (e.g., hemp powder, hemp protein) in Japan. The hope is that global food manufacturers may become more interested in hemp seed as an ingredient.

For example, in the global beverage industry there is a category often called “relaxation drinks”, marketed as an alternative to high-caffeine coffee and energy drinks. This is a potentially large category, as not only soft drinks but also alcohol and beer brands are developing products for this category. Endian LLC, funded partially by Coca Cola Bottlers Japan Inc. recently released a drink called “Chill Out” in Japan, available for 200 JPY (\$1.80) in shops and vending machines. The drink contains some hemp seed, as well as GABA and is being marketed as a relaxation beverage. It was aggressively promoted in May 2021 on the video advertising screens on Tokyo train lines.

While the amount of hemp seed used in the Chill Out product is minimal, Japan’s hemp product industry took this launch of a product with hemp seed as a sign that the biggest players like Coca-Cola are eyeing the hemp industry – be it seed, oil, CBD, or other extracts – as a new trend in food and beverage products and a sign of a potentially much larger market for hemp seed in the future. If Japan’s import process were not as slow and risky, importers also felt there would be a much bigger market.

### **3.2. JAS Organic**

The Japanese Agricultural Standard (JAS) Organic label is a certification mark given to agricultural products that have been certified to meet organic standards set by the Ministry of

Agriculture, Forestry and Fisheries (MAFF).

Since 2014, Japan recognizes the U.S. National Organic Program's (NOP) organic standards for plants and plant-based processed products as equivalent under U.S.-Japan Organic Equivalency Arrangement, so NOP- certified U.S. products do not need to undergo a separate JAS organic certification process, and can be sold as organic in the Japanese market. MAFF confirmed that hemp products are covered by the U.S.-Japan organic equivalency arrangement.

The organic market in Japan is very small compared to the United States and the EU<sup>2</sup>. In Japan, the concept of organic is tied more to an image of safety and quality among consumers than ideas of sustainability or eco- friendliness. There is some evidence that this perception may be evolving, along with global industries' commitments to sustainability.

According to industry contacts, hemp seed product consumers tend to be health-conscious and with a preference for organic products. In the hemp seed market in particular, the products for sale are currently concentrated in the health food sector and quite a number, especially those sourced from the EU, carry a JAS Organic seal, under the EU-Japan equivalency agreement. Consumers may consider an organic label a positive aspect of the product, but organic is not considered a marketing requirement by hemp product industry experts.

### **3.3. Hemp Seed Cake**

There is no hemp seed cake market in Japan and no known imports at this time. MAFF reports that it does not have any specific approval process for this kind of animal feed and indicated that it would be legally possible to develop a hemp seed cake market.

Japan Customs confirmed that imports of hemp seed cake would need to follow the same rules as hemp seed, assuming the ingredients are purely ground hemp seed or its byproduct. As with hemp seed, the product would need to confirm compliance with the Plant Protection Act. In addition, if it was meant for animal feed, it would need to conform to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, which controls aspects of pet and animal feed.

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<sup>2</sup> <https://www.fas.usda.gov/data/japan-organic-market-review-2021>

## 4. Hemp Seed Import Regulations

Hemp seed is allowed to be imported under the Cannabis Control Act. However, importers of hemp seed as food or food ingredients are required to verify that their products are heat-treated hemp seed under the Foreign Exchange and Foreign Trade Act. Heat treatment is necessary to prevent seeds from germination. This is done by submitting the required heat treatment certifications as well as the importer's "request for certification" to MHLW stating "These hemp seeds are heat treated. Please allow them to pass customs".

Heat treatment is normally done in the exporting country and this is the strong preference of MHLW, but it is possible for heat treatment to be conducted in Japan. If the heating treatment is conducted in the exporting country, the manufacturer must provide a document certifying the heat treatment, as well as a document which describes the heat treatment process. MHLW recommends heating hemp seeds to at least 90 degrees Celsius for at least one hour.

If an importer decides to conduct the heat treatment in Japan, the importer must include the name of the heat treatment company they have chosen in their request for certification of heat treatment. When the hemp seeds arrive in Japan, the designated heat treatment company will conduct the treatment under the supervision of MHLW. There is no specific regulation about the location of the heat treatment facility, and they can be treated outside the bonded area. After the heat treatment, the seeds will remain at the heat treatment facility while MHLW performs the germination test. There is no need to transport the treated seeds back to the port.

MHLW conducts a germination test on all shipments, regardless of where the heat treatment was conducted. The germination tests are not conducted at the ports, but at the facilities of regional offices of MHLW. MHLW has offices throughout Japan and there is no restriction on which ports to use for importation of hemp seeds.

The germination test takes about 1-2 weeks, but MHLW cannot guarantee how soon the test will be conducted after the products arrive in Japan or after heat treatment is completed in Japan. MHLW regional offices will collect samples for the germination test, usually about 100 grams. However, if the seeds were heat treated in multiple batches or are from multiple production areas or harvests, a sample will be collected for each type.

If the seeds pass, MHLW will issue a heat treatment approval certificate to the importer verifying that the hemp seeds did not germinate. The importer will submit this certificate to Customs.

The same regulations and process apply whether the hemp seed is destined for human or animal use.

The key laws regulating hemp seed imports are the Foreign Exchange and Foreign Trade Act (regarding the heat treatment), the Cannabis Control Act (no leaves, buds or flowers are mixed with the shipment), the Plant Protection Act (regulating the pest and disease entry into Japan) and the Food Sanitation Act.

Hemp seed importers report much longer wait at Customs than usual in the past year or so, due to the increase in hemp seed imports, which all require germination tests. The longer wait time is also reportedly affected by the increase in imports of CBD products, which has led to much closer inspections for all hemp-derived products. The wait to clear hemp seed can be up to two months. This is putting pressure on ready-to-eat food products which contain hemp seeds, such as health bars containing seeds, because Japanese retailers require at least 60-70 percent of shelf life left on the expiration date.

### **What happens to an importer whose shipment of hemp seed products is rejected?**

Hemp seed importers have reported cases of hemp seed imports that were not appropriately heat treated as discovered during the germination test. In those cases, importers had to write a letter of explanation to MHLW. This risk has reportedly made the larger Japanese trading companies hesitant to enter this niche health food sector.

If the seeds were heat treated in the U.S. and do not pass the Japanese germination test, they can be sent back to the United States for heat treatment again and re-sent to Japan. Importantly, seeds treated in the United States which fail the germination test cannot then be heat treated in Japan.

If the original heat treatment was conducted in Japan and the seeds fail the germination test, heat treatment can be conducted again in Japan and the seeds retested. However, MHLW strongly recommends doing all heat treatment in the country of origin and not in Japan.

There also are reported cases where illegal cannabis plant parts (e.g., leaves) were found in a seed shipment. These products were not permitted to be imported and the shipment was destroyed. These cases required a letter of explanation from the importer to MHLW.

## 5. Importing Hemp Seed: Step-by Step Guide

Summary of the Steps to take to export a hemp seeds or products with hemp seeds to Japan  
(Steps Highlighted in Red are Specific to Hemp Seeds)

### A. Pre-Embarkation

- ❑ 1. Prepare an Ingredient List and a Manufacturing Process Flowchart
- ❑ 2. Check any phytosanitary requirements that apply to your product
- ❑ 3. Confirm legal compliance with food standards. Also check with additives restrictions and other regulations, such as sanitary requirements if the seeds are an ingredient in a food product
- ❑ 4. Double check the tariff classification and customs duty with your importer
- ❑ 5. Create a product label
- ❑ 6. Register trademarks and other intellectual property rights for retail-ready products

### B. Embarkation

- ❑ 7. Obtain Certification that the seeds were heat treated\*
- ❑ 8. Provide a letter that outlines the heat treatment process\*
- ❑ 9. Clear export customs

### C. Import Clearance

- ❑ 10. Your importer will submit the following documents to MHLW:
  - Certificate that the Seeds were Heat Treated
  - Letter documenting the method of the heat treatment
  - Importer's "Request for certification of heat treatment"
  - Importer's company registration certificate
  - Documentation showing the flight or ship the seed product is arriving on
- ❑ 11. Seeds will be tested for germination and be issued a certificate of heat treatment approval after passing.
- ❑ 12. Clear phytosanitary inspection if required for your product
- ❑ 14. Clear food safety quarantine procedure
- ❑ 15. Have importer submit certificate of heat treatment approval to Customs
- ❑ 16. Clear import customs

*\*As mentioned earlier, Step 8 and 9 can be conducted in Japan if desired by exporter and importer. However, MHLW recommends conducting heat treatment in the exporting country.*

## 6. Hemp Seed Oil Market and Trends

There are no specific import statistics related to hemp oil as it is imported under HS Code 1515.90, which covers many oil products. Japan Customs confirmed that more detailed data is not currently available.

In retail, hemp seed oil products can be found from Australia, New Zealand, Lithuania, Canada and the United States, but brands are limited. They are found primarily in e-commerce and in health food sections of shops.

In e-commerce, in particular, there can be some inconsistency in consumer labelling. Both hemp seed oil and CBD oil products are sometimes labeled “hemp oil”. The words “hemp” and “CBD” are sometimes used interchangeably in labelling and marketing on CBD-oriented brands found in the Japanese market. However, the import regulations for oil containing CBD and hemp seed oil (non-CBD) are different. For requirements for products containing CBD, please refer to *The Japanese Market for CBD and Hemp Extracts*.

Industry players did not feel the hemp seed oil market is quickly growing, but it could have good potential to grow with increased awareness of the purported health benefits of the seeds and oil.

### 6.1. Hemp Seed Oil Import Regulations

Unlike for CBD products, MHLW has not released a memo on the specific steps for importing hemp oil, which is still a very niche product. As a result, some documents which are not legally required for hemp seed oil, (such as a Substance Analysis Report for non-detection of THC, as required for CBD products) are still suggested by MHLW to be obtained in the exporting country and included with Customs documents “if possible”. Please refer to Appendix 1 of *The Japanese Market for CBD and Hemp Extracts* report for more details of what a Substance Analysis Report for CBD imports includes.

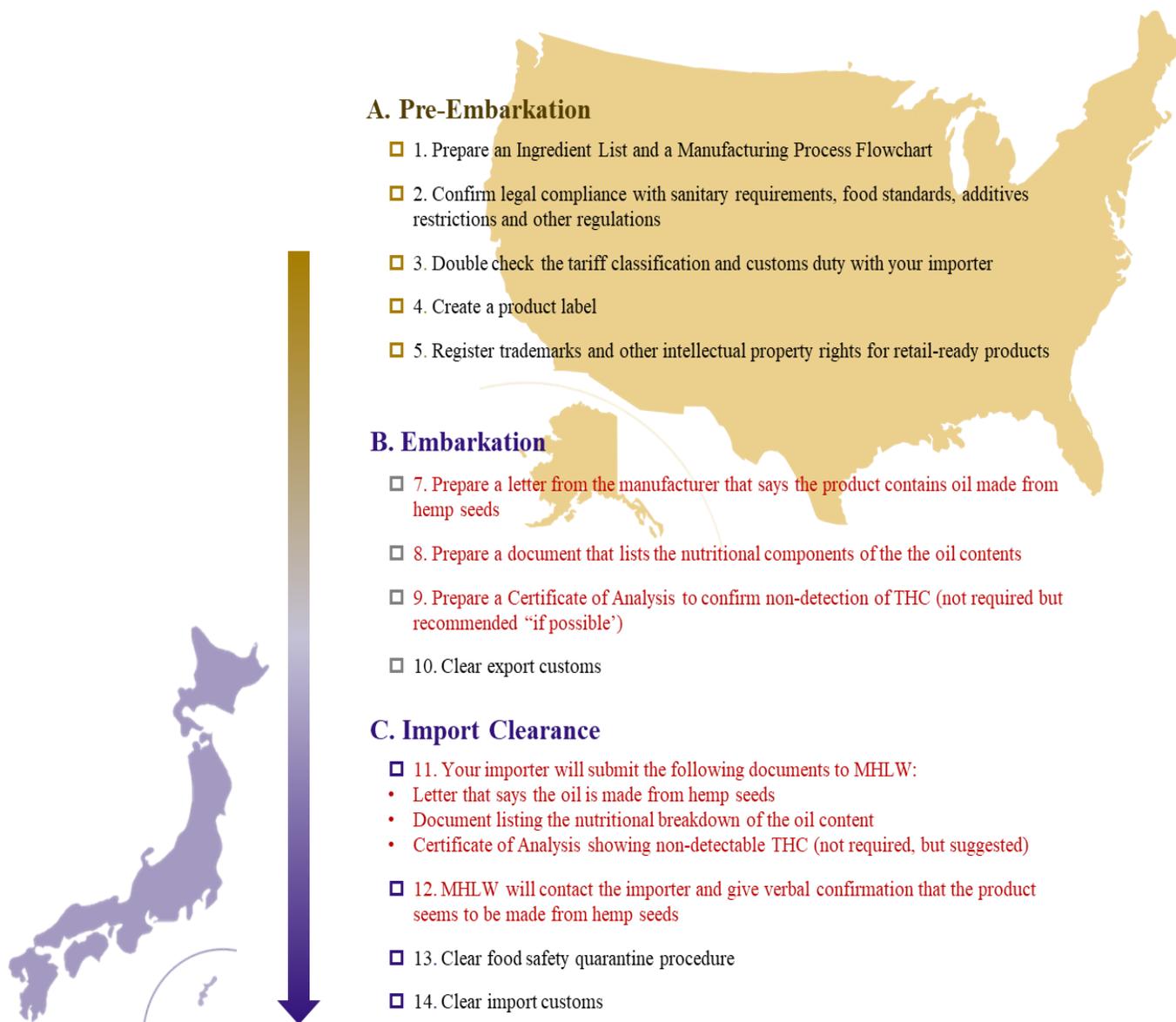
Close communication with the importer, especially on the first shipments of hemp seed oil to Japan, is particularly important to ensure that all required documents are submitted.

Hemp seed oil regulations are relevant even if the product is not pure hemp seed oil and is mixed with other oils or ingredients.

Hemp seed oil sold as capsules or gummies will need to follow hemp seed oil regulations as well as relevant packaged food product regulations, depending on the other ingredients in the product. In these cases, it will be important to confirm with your importer about the correct HS Code and packaged food category requirements.

## 7. Importing Hemp Seed Oil: Step-by Step Guide

Summary of the Steps to take to export a Hemp Seed Oil product to Japan  
(Steps Highlighted in Red are Specific to Hemp Seed Oil)



## 8. Appendix 1: Laws and Regulations relevant to Import of Hemp Seed and Hemp Seed Oil Products

Below are the importation laws and regulations relevant to hemp seed and hemp seed oil products.

### 8.1. 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 and the term “narcotics” follows the definition laid out in the Narcotics and Psychotropics Control Act.

Hemp seed and hemp seed oil are not prohibited under the Cannabis Control Act.

#### **The Customs Act is available at:**

The Customs Act (Act No. 61 of 1954)

In Japanese, the link below is the March 31, 2020 version (reflecting the latest revision)

[https://elaws.e-gov.go.jp/search/elawsSearch/elaws\\_search/lsg0500/detail?lawId=329AC0000000061\\_20191216\\_501AC0000000016&openerCode=1#AB](https://elaws.e-gov.go.jp/search/elawsSearch/elaws_search/lsg0500/detail?lawId=329AC0000000061_20191216_501AC0000000016&openerCode=1#AB)

In English, the link below is the March 31, 2020 version (reflecting the latest revision), translated by Japan Tariff Association.

[https://www.kanzei.or.jp/kanzei\\_law/329AC0000000061.en.html](https://www.kanzei.or.jp/kanzei_law/329AC0000000061.en.html)

#### **Responsible government agencies**

Japan Customs, Japanese Ministry of Finance

<https://www.customs.go.jp/> (Japanese)

Contact details for the nine regional Customs offices are available at:

[http://www.customs.go.jp/question\\_e.htm](http://www.customs.go.jp/question_e.htm) (English)

## 8.2. 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 Cannabis Control Act defines the term ‘cannabis’ as “the cannabis plant (*Cannabis sativa* L.) and its products. The Act however excludes from the definition of “cannabis”, the mature stalks<sup>3</sup> of the cannabis plant and its products (excluding resin) as well as the seeds of cannabis plants and its products. [Article 1].

As a result, this Act does not prohibit hemp seed and hemp seed oil products from import to Japan.

However, any contamination of a hemp seed shipment with leaves, flowers or buds would be in violation of the Cannabis Control Act and would not be permitted. There is zero tolerance for THC, which is why some importers will recommend a Certificate of Analysis to show non-detection of THC in hemp oil products.

### 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: <https://elaws.e-gov.go.jp/document?lawid=323AC0000000124>

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:

[http://www.japaneselawtranslation.go.jp/law/detail\\_download/?ff=09&id=2594](http://www.japaneselawtranslation.go.jp/law/detail_download/?ff=09&id=2594)

### 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,

[https://kouseikyoku.mhlw.go.jp/kantoshinetsu/gyomu/bu\\_ka/mayaku\\_torishimari/index.html](https://kouseikyoku.mhlw.go.jp/kantoshinetsu/gyomu/bu_ka/mayaku_torishimari/index.html) (Japanese)

Phone: +81-3-3512-8688 (Japanese only)

Email: [CHECKCBD@mhlw.go.jp](mailto:CHECKCBD@mhlw.go.jp) (Japanese only)

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<sup>3</sup> There is no definition of “mature” or “grown” stalks. However, based on the judicial precedent, MHLW interprets “grown stalk of cannabis” 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”. (GAIN Report, JA2020-0190: [Japanese Import Regulations for Industrial Hemp Products](#))

### **8.3. The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and 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 the MHLW.

This act is relevant for hemp seed and oil products that would be marketed as animal feed or feed supplements, as this Act regulates aspects of pet and animal feed.

#### **Hemp Products for Animals**

Veterinary medicines and quasi-drugs for animals are regulated under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. 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).

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

In Japanese, the December 4, 2019 version is the latest revision.

[https://elaws.e-gov.go.jp/search/elawsSearch/elaws\\_search/lsg0500/detail?lawId=335AC0000000145](https://elaws.e-gov.go.jp/search/elawsSearch/elaws_search/lsg0500/detail?lawId=335AC0000000145)

For English, the link here is 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. It is the Ministry of Justice's unofficial translation.)

<http://www.japaneselawtranslation.go.jp/law/detail/?id=3213&vm=04&re=01>

#### **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:

<https://www.yakujihou.com/co/link.html> (Japanese)

## 8.4. 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.<sup>4</sup> The Act establishes the sanitary standards for food products and the importer must 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 hemp. However, substances without a set limit are subject to the default MRL of 0.01 parts per million (ppm).

### The Act is available at:

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

For Japanese, the link below is the June 15, 2018 version (reflecting the latest revision):

[https://elaws.e-gov.go.jp/search/elawsSearch/elaws\\_search/lsg0500/detail?lawId=322AC0000000233](https://elaws.e-gov.go.jp/search/elawsSearch/elaws_search/lsg0500/detail?lawId=322AC0000000233)

For English, this is the link to the Ministry of Justice’s unofficial English translation of the June 7, 2006 version:

<http://www.japaneselawtranslation.go.jp/law/detail/?id=12&vm=04&re=01>

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<sup>4</sup> Pharmaceutical or quasi-pharmaceutical products are defined by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices [Article 4].

## 8.5. The Plant Protection Act

The Plant Protection Act aims to control plant diseases and pests and prevent the outbreak or spread in Japan and is under the jurisdiction of MAFF.

This Act lays out the requirements for inspection and control of plant products imported into Japan.

### **The Plant Protection Act is available here:**

For Japanese, a link to the law can be found here:

<https://elaws.e-gov.go.jp/document?lawid=325AC0000000151>

For English, the link here is the Ministry' of Justice's unofficial translation of the 2005 amended version. There is no Ministry of Justice translation of the most recent 2019 version.

<http://www.japaneselawtranslation.go.jp/law/detail/?id=25&vm=02&re=02&new=1>

### **Responsible Government Agencies**

Contacts for Plant Protection Stations under MAFF can be found here:

English [https://www.maff.go.jp/pps/j/introduction/english\\_exp.html](https://www.maff.go.jp/pps/j/introduction/english_exp.html)

Japanese: <https://www.maff.go.jp/pps/j/guidance/outline/contact.html>

## 8.6. The Foreign Exchange and Foreign Trade Act

The Foreign Exchange and Foreign Trade Act controls and coordinates foreign transactions, such as foreign exchange and foreign trade. It is also under this Act that hemp seeds must be heat treated.

Based on Article 52 of the Act, the Cabinet issued the Import Trade Control Order in 1949 to regulate trade and imports. Under Article 3 of this Order, a Ministerial Order titled Public Notice No. 170 of the Ministry of International Trade and Industry of 1966 was issued. Article 8 (1) of this Ministerial Order states that in order to import hemp seeds, documentation is required proving that the hemp seeds have been heat treated.

### The Act is available here:

For Japanese, a link to the Act can be found at  
<https://elaws.e-gov.go.jp/document?lawid=324AC0000000228>

For English, a link to the Act can be found at  
<http://www.japaneselawtranslation.go.jp/law/detail/?id=3267&vm=04&re=01>

### The pursuant Orders can be found here:

Import Trade Control Order  
<http://www.japaneselawtranslation.go.jp/law/detail/?id=3827&vm=&re=>

Public Notice No. 170 of the Ministry of International Trade and Industry of 1966. See Article 8 (1) for hemp seed regulation.  
[http://www.japaneselawtranslation.go.jp/common/data/notice/143117\\_m.html](http://www.japaneselawtranslation.go.jp/common/data/notice/143117_m.html)

### Responsible Government Agencies

Ministry of Finance  
Phone: +81-3-3581-4111  
<https://www.mof.go.jp/english/index.htm>

Trade Control Division, Trade Control Department, Trade and Economic Cooperation Bureau,  
Ministry of Economy, Trade and Industry (METI)

Phone: +81-3-3501-0538  
<https://www.meti.go.jp/english/index.html>

### Attachments:

No Attachments.