

# Cannabis and Hemp Business Guide – Thailand

## Authors

- |                    |  |
|--------------------|--|
| Alan Adcock        | • <a href="mailto:alan.a@tilleke.com">alan.a@tilleke.com</a>           |
| Atthachai Homhuan  | • <a href="mailto:atthachai.h@tilleke.com">atthachai.h@tilleke.com</a> |
| San Chaithiraphant | • <a href="mailto:san.c@tilleke.com">san.c@tilleke.com</a>             |

## Introduction

Cannabis (also known as marijuana) and hemp have been classified as a category 5 narcotic under the Narcotics Act since 1979. All activities related to the plants and their derivatives had been very much restricted until the recent rise of the cannabis legalization movement—its first milestone being Amendment (No. 7) to the Narcotics Act, effective February 19, 2019. The Thai government has since been working to reclassify the products and lay out the regulatory pathways to accommodate these new “economic plants.”

Most of the product classifications discussed here are based upon the tetrahydrocannabinol (THC) content, and upon the presence of cannabidiol (CBD) in the products. Generally speaking, THC is a psychoactive substance with fewer medical applications, while CBD is not psychotropic and has more medical applications. A higher THC content is therefore associated with a greater risk of abuse, and thus stricter regulations apply. Under the most recent legal amendments, Thai law defines cannabis as plants in the *Cannabis* genus, and hemp as *Cannabis sativa* L. subsp. *sativa* having no more than 1.0 % THC by dry weight in its leaves and inflorescence.

The key regulator of cannabis- and hemp-related products is the Thai Food and Drug Administration (Thai FDA), a government agency operating under supervision of the Ministry of Public Health. Working closely with the Narcotics Control Committee, the Thai FDA is mainly responsible for granting and administering licenses and post-marketing control, among others. Representatives of the Thai FDA also sit on most of the national policymaking committees.

The Thai government considers cannabis legalization a complex task affecting diverse groups of stakeholders. Notable stakeholders include parties involved in both upstream and downstream production, healthcare professionals, hospitals, consumers or patients, and regulatory authorities, both in Thailand and overseas. Traditional medicine practitioners are an additional and particularly influential group of stakeholders, unique to Thailand, as they utilize longstanding traditional formulations containing cannabis.

The Thai government has adopted a protective stance toward Thai stakeholders—especially during the first stage of cannabis legalization, which runs until 2024. During this first stage licenses with respect to cannabis will only be granted to state agencies, and therefore a private entity or group of farmers is only eligible for a cannabis license if they operate jointly with a state agency. This requirement does not apply to the hemp licensing framework, wherein a private entity may apply for and hold a hemp license independently.

## Key Dates

- April 28, 1979** The Narcotics Act (No. 1) took effect, declaring (*inter alia*) cannabis and hemp as a category 5 narcotic.
- January 28, 2019** The National Council for Peace and Order's Ordinance No. 1/2562 became effective, rejecting Thai patent applications related to cannabis (see also **Intellectual Property**, below).
- February 19, 2019** The Narcotics Act amendment (No. 7) came into effect, legalizing medical cannabis (both cannabis and hemp) as the first milestone of the cannabis legalization movement.
- March 30, 2019** A ministerial notification took effect setting out 16 cannabis-containing Thai traditional medicine formulations that may be consumed for therapeutic purposes without having to be registered with the Thai FDA.
- May 21, 2019** End of the "amnesty period," during which persons possessing cannabis for certain purposes (medical, research, etc.) could declare their possession to the Thai FDA and be exempted from criminal punishment.
- August 7, 2019** The Government Pharmaceutical Organization launched the first batch of medical CBD oil, THC oil, and CBD:THC oil (4,500 units of 5 milliliters each) for the special access scheme (SAS) in public hospitals.
- December 14, 2020** The "delisting" ministerial notification became effective, carving out domestically produced items containing certain cannabis plant parts, certain hemp plant parts, and CBD extract with less than 0.2% THC by weight, from the scope of Narcotics Act (see also **Product Classification**, below). Importation of these products still requires an importation license as prescribed in the Narcotics Act.
- January 29, 2021** The Hemp Regulation RE: Application of the License and Issuing of Licenses to Manufacture, Import, Export Disposal or Possession of Hemp took effect, allowing cultivation for production of modern drugs, herbal products, cosmetics, and food products, as well as for household and certain other uses. More importantly, unlike under the cannabis regulations, private entities established in Thailand and groups of farmers (e.g., those established as a cooperatives or community enterprises) can obtain licenses independently without the need to form a partnership with a state agency.

## Product Classification

No.	Relevant Product	Status	Governing Law	Definition	Remarks
1	Whole cannabis/hemp plant, cannabis seeds, resins, and oleoresin	Handling requires regulatory approval	Narcotics Act	Cannabis: Plants in <i>cannabis</i> genus  Hemp: <i>Cannabis sativa</i> L. subsp. <i>sativa</i> having $\leq$ 1.0% THC	-
2	Parts of cannabis and hemp plant	Deregulated	-	Bark, stems, fiber, branches, roots, and fan leaves	Inflorescence of cannabis and hemp is still a narcotic
3	Hemp fiber product	Deregulated	-	-	-
4	Isolated CBD	Handling requires regulatory approval	Medical Device Act (reagent for test kit)	For use as a reference standard in quality control, or for use as a reagent in in-vitro test kit (medical device)	-
5	Modern drug with THC >0.2% by weight	Handling requires regulatory approval	Narcotics Act	-	-
6	Modern drug (medical cannabis or medical hemp with $\leq$ 0.2% THC by weight)	Handling requires regulatory approval	Drugs Act	Modern drug formulation having $\leq$ 0.2% THC	-
7	Herbal cannabis or hemp products (e.g., cosmeceuticals, nutraceuticals)	Handling requires regulatory approval	Herbal Products Act	Herbal products having $\leq$ 0.2% THC	Importation of products is licensed under the Narcotics Act.
8	Cosmetics containing hemp seed oil or extract	Handling requires regulatory approval	Cosmetics Act	Containing hemp seed oil or hemp seed extract	Importation of products is licensed under the Narcotics Act.
9	Food, beverages, and food additives containing hemp seed oil or extract	Handling requires regulatory approval	Food Act	Containing hemp seed or hemp seed oil	Importation of products is restricted and is licensed under the Narcotics Act.
10	Recreational cannabis	Banned	Narcotics Act	-	-

## Activity-Focused Regulatory Overviews

### Cultivating Cannabis

The cultivation of cannabis (see **Product Classification**) requires a production license from the Thai FDA under the Narcotics Act. Currently, licenses have been granted to state agencies, such as the Government Pharmaceutical Organization, universities, government research institutions, and public hospitals. Licensing rules and procedures for private companies will be implemented by the now-pending ministerial regulation. In any case, an exclusivity period applies until February 19, 2024, during which only the Thai government and its partners have standing for a commercial license, but a non-commercial license (e.g., for research and development) may be issued for other applicants.

### Cultivating Hemp

The cultivation of hemp (see **Product Classification**) also requires a production license from the Thai FDA under the Narcotics Act. Licensing rules and procedures for private parties are set out in the new Hemp Regulation that took effect on January 29, 2021. Unlike cannabis, cultivation of hemp does not fall within an exclusivity period for state agencies. If hemp seeds are to be imported for cultivation, an importation license must first be obtained according to the Narcotics Act.

### Importing or Producing Medical Cannabis

Notable examples of medical cannabis (see **Product Classification**) include cannabis oil and Thai traditional medicines with cannabis plant parts as ingredients. For production or importation of medical cannabis containing more than 0.2% THC by weight, regulatory approval (i.e., licensing) from the Thai FDA is required under the Narcotics Act. For production, licenses have been granted to the Government Pharmaceutical Organization, government research institutions, public hospitals, and qualified practitioners of modern or Thai traditional medicine. A state-agency-only exclusivity period applies until February 19, 2024, during which only the Thai government and its partners have standing for a commercial license, while non-commercial licenses (e.g., for research and development) may be issued to other applicants.

### Importing or Producing Modern Drugs Formulated with Cannabis, Hemp Extract, or Other Cannabinoids

Modern drugs formulated with cannabis, hemp extract, or other cannabinoids with less than 0.2% THC (see **Product Classification**) require regulatory approval (i.e., licensing) from the Thai FDA under the Drugs Act. The licensing rules and procedures are already in place per the existing ministerial regulations and notifications issued pursuant to the Drugs Act. Notably, a drug manufacturer or importer license is required for the business operator, and a drug registration certificate is required to market a particular modern drug formulation.

## **Importing or Producing CBD-Infused Traditional Drugs, Cosmeceuticals, or Nutraceuticals**

These products are considered herbal products (see **Product Classification**). For domestically produced goods, regulatory approval (i.e., licensing) from the Thai FDA is required under the Herbal Products Act. Importation of these products into Thailand must follow the Narcotics Act's licensing rules and procedures. Additionally, the product must comply with the specifications to be prescribed by the pending ministerial notification expected to be issued in 2021.

## **Importing or Producing Cosmetics Formulated with Hemp Seed Oil or Extract**

Domestically produced cosmetics formulated with hemp seed oil or extract (see **Product Classification**) require regulatory approval (i.e., licensing) from the Thai FDA under the Cosmetics Act. However, importation of these products into Thailand must follow the Narcotics Act's licensing rules and procedures. Additionally, the product must comply with the specifications prescribed by Ministerial Notification RE: Use of Hemp in Cosmetics 2020.

## **Importing or Producing Food, Beverages, or Food Additives Formulated with Hemp Seeds or Hemp Seed Oil**

These products are considered food (see **Product Classification**). For domestically produced goods, regulatory approval (i.e., licensing) from the Thai FDA is required under the Food Act. On the other hand, importation of these products into Thailand must follow the Narcotics Act's licensing rules and procedures. Additionally, the product must comply with the specifications to be prescribed by the pending ministerial notifications expected to be issued in 2021.

## **Using Non-narcotic Hemp in Food**

While not yet allowed, on March 4, 2021, the Ministry of Public Health released a draft notification that will concern hemp seeds, hemp seed oil, or hemp seed proteins, and food containing ingredients thereof. According to this draft notification, hemp seeds, hemp seed oil, and hemp seed proteins are the only parts of hemp plants that will be allowed for use in a food formulation after the official issuance of the notification, which will also set out the allowable specifications. The hemp seeds or hemp seed oil will have to be obtained from hemp produced in Thailand.

# **Intellectual Property**

## **Patents**

On January 28, 2019, the Thai government issued a quasi-emergency ordinance to reject a number of Thai patent applications filed by foreign applicants, all of which related to medical formulation or use of cannabis-derived active ingredients. The ordinance was issued to annul any private exclusive rights that could block access to medical cannabis following the legalization, and it was terminated on February 19, 2019, when cannabis legalization took effect. Since then, patentability has been once again examined against the previously established rules of the Patents Act. Generally,

an application related to cannabis is eligible for a patent if it is not for recreational purposes; not a diagnostic or therapeutic method; and not the plant itself, its part, or mere crude extract.

### **Trademark**

Generally, marks for use with goods or services related to the legalized use of cannabis or hemp are registrable as Thai trademarks. On the other hand, marks related to cannabis itself (e.g., images of a cannabis leaf) are not registrable, irrespective of the goods or services.

