

# Guidelines to be followed by CBD service and hemp-related service providers

Japan Industrial Hemp Association  
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## **Chapter 1 : About these guidelines**

### **1. Background and history**

Medical expenses in Japan have continued to expand in recent years, reaching 42.2 trillion yen in 2020. In addition, the recent spread of the new coronavirus has placed a heavy burden on medical facilities, making self-medication increasingly important. CBD is expected to contribute to self-medication for minor symptoms, and hemp is also expected to be an extremely important plant for achieving the SDGs (Sustainable Development Goals). Regulations on the parts of cannabis have been abolished and replaced with component regulations, and it is expected that many businesses will enter the market in the future. On the other hand, strict handling is required, and from the perspective of consumer protection, businesses are required to establish strict import, inspection, manufacturing, and sales systems as well as systems for information disclosure. Against this background, we established the Japan Hemp Association (General Incorporated Association) in May 2022 with the aim of creating a market where individuals and companies can safely choose services based on appropriate information and options. We are currently formulating guidelines that must be followed in order to gain consumer trust and establishing a certification system. In formulating the guidelines, we have established a voluntary standards committee to ensure that the content of the operating system and information disclosure of business operators is required from the perspective of individuals and companies who use the service, from the viewpoint of transparency, objectivity, and objectivity. , established a regular consultation process and developed guidelines. In addition, the guidelines created were verified (from business perspectives, consumer perspectives, and advice from experts/experts, etc.), and the guidelines were compiled.

### **2. Purpose of formulating guidelines**

The first edition of the guidelines (general provisions) to encourage CBD service providers and hemp-related service providers to clearly and appropriately disclose test results and other necessary information to consumers. has been formulated. We hope that this will create a situation where consumers can easily understand the reliability of information, avoid being misled by unsubstantiated information and displays, and be able to correctly select services that are appropriate for their purposes. In order to protect consumers and support the health of the nation, our association adheres to guidelines that contribute to the development of the industry and industries, promotes information dissemination activities including guidelines, and promotes CBD services and hemp-related service businesses. We will strive to

### **3. Scope of application of the guidelines**

These guidelines are established as specific guidelines to help businesses providing CBD services and hemp-related services to accurately convey information to consumers. Members of our association and businesses providing CBD services and hemp-related services must fully understand the content and purpose of the guidelines, and strive to comply with the guidelines to avoid any acts that violate relevant laws and regulations. I would like to have it. Please note that this guideline will continue to be revised from time to time as necessary.

#### 4. Definition of CBD services and hemp-related services

CBD services and hemp-related services refer to all products and services that consumers can use at home or at work to improve their health, improve their QOL (Quality of Life), or self-medicate. The scope of services excludes medical-related activities (medical treatment and diagnosis at hospitals and clinics, pharmaceuticals and medical devices such as prescription drugs and OTC drugs, and treatment and prevention of diseases). , to help improve one's health.

CBD services can be classified into the following categories, for example:

Large category	Small category		Small category details
material*1	CBD isolate		Each cannabinoid extracted from cannabis
	CBG		
	CBC		
	CBN		
	broad spectrum		All ingredients extracted from cannabis (those with THC removed)
	Full Spectrum *Not available domestically		All ingredients extracted from cannabis (including THC)
product	food	Oil/Tincture	Sublingual Oil
		supplements	capsule etc.
		Confectionery	Gummies, sweets, etc.
	cosmetics	skin care	Beauty serums, creams, etc.
		body care	cream etc.
	miscellaneous goods	Non-cosmetic products	bath salts etc.
		grocery item	vaping etc.

\*1 · Raw materials are classified according to whether the import item is cosmetics or food, and the imported items are the same.

\*Hemp-related services will be defined based on future service development.

#### 5. Guidelines operational system

Businesses participating in this association shall comply with the guidelines, strive to develop and develop healthy and appropriate businesses based on the understanding of society, and strive to earn trust from ethical, legal, and social aspects. The organization is currently working on its own initiative and will carry

out the following activities.

- (1) Research and information dissemination and provision related to CBD services and hemp-related services
- (2) Creation of guidelines, etc., and dissemination and provision of information related to CBD services and hemp-related services
- (3) Investigation, research, development and support for quality improvement and performance evaluation of CBD services and hemp-related services.
- (4) Activities for information exchange and collaboration/cooperation with related organizations, related ministries, local governments, etc.
- (5) Promotion of quality labeling of CBD services and hemp-related services and issuance of mark labels, etc.
- (6) Establishment and operation of electronic media such as websites, exchange places, seminars, etc. for the dissemination and provision of information, and editing and publication of journals and other publications.
- (7) Other activities necessary to achieve the objectives of the association

Business operators participating in the association are organized in a manner that covers a wide range of industries and is comprised of stakeholders who have an influence on the industry. In addition to implementing the guidelines in a multifaceted and effective manner, we will also build a cooperative system for their dissemination after they are formulated.

In addition, in order to avoid bias toward the business perspective, we not only conduct research and verification from the consumer's perspective, but also conduct research and verification work that includes advice from experts and experts regarding guidelines, etc. within and outside the industry, as necessary. We will carry out the work. In addition, from the perspective of transparency, it is desirable that the information be published on the association's website and also on the websites and product pages of each business operator.

## **6.Board of Trustees**

Invite fair and neutral experts from a variety of positions to participate and listen to opinions based on the content of CBD services and hemp-related services.

<Role of the Board of Councilors>

- ① At the request of the Board of Directors, the Board of Directors may examine the suitability of a project carried out by a business operator from scientific, ethical, legal, social, and technical perspectives, and provide opinions to the business operator.
- ② The board shall be appropriately structured and operated so that fair and neutral examinations and advice can be provided by councilors from a variety of positions, from an independent standpoint and from a pluralistic perspective.

③ Councilors must not divulge information obtained in the course of their duties without justifiable reason.

<Purpose of the Board of Councilors>

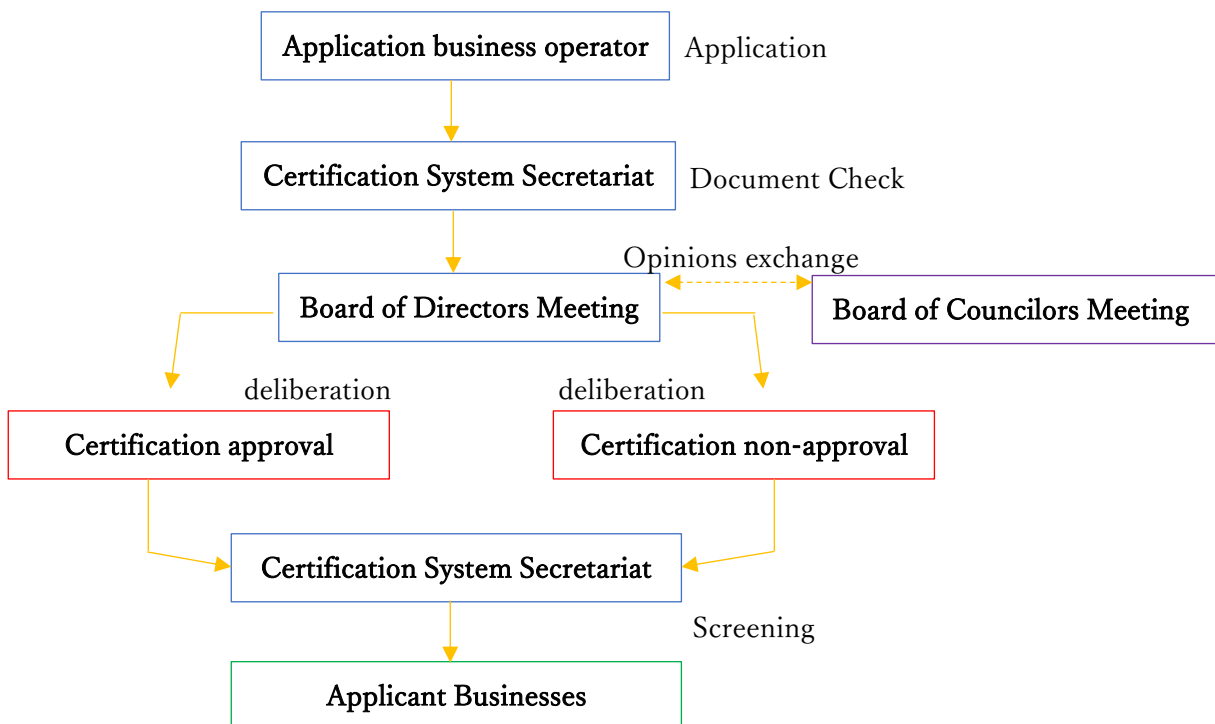
① Provide advice to our association as an independent association

② Provide advice during the examination process of the certification system

### 7. Confirmation of compliance status of guidelines (certification system)

Since there is a need for a system to evaluate the status of compliance with these guidelines, the association will launch a certification system and, as an industry organization, will establish a system to operate and continuously check the certification system. Regarding certification standards, we will establish separate items for confirmation and implement them appropriately, taking into account the opinions of the certification committee, board of councilors, etc. established by our association. The association's certification system evaluates whether a business has properly developed the products and services it provides, based on the status of overseas inspections and permits when importing, the status of domestic inspections and their results. The decision shall be made comprehensively, taking into account the status of compliance with the guidelines, etc. Depending on the certification system and the compliance status of businesses after certification, there is a risk that the credibility of the industry as a whole may be damaged, so compliance status will be regularly monitored and disclosed as necessary. In addition, if it is confirmed that the business is not in compliance, the association will issue a warning to the business operator and request improvements as necessary. If no improvements are made, we will consider withdrawing the certification.

### 8. Certification system examination flow (image)



## Chapter 2 : Compliance matters

### 1.Responsibilities of business operators

Businesses that provide CBD services and hemp-related services should strive to cooperate with businesses and related parties across the industry to provide better CBD services and hemp-related services to consumers.

### 2.Clarification of service content

When consumers select and use a service, they should be aware of the content of the service (such as dosage) and how the service will help them improve their health, without any falsehoods or exaggerations. be clearly and clearly stated in a way that is easy for consumers to understand.

### 3.Storage and management of product-related documents, including import-related documents, and establishment of a domestic inspection system

Providing appropriate information to consumers so that they can make appropriate decisions when providing products and services. It is extremely important to do so. It is desirable for businesses to comply with related laws, regulations, standards, etc., and provide appropriate information to consumers.

Based on this, we will recommend the storage and management of product-related documents, including documents related to import procedures, and domestic inspections, and build a system that allows for appropriate information disclosure. The following are examples of documents that need to be stored and managed.

#### <About required documents>

Required documents	Name of documents	Remarks
	Certificate and image confirming the CBD extraction site	Documents submitted to the Narcotics Control Department of the Ministry of Health, Labor and Welfare
	Image of cannabis plant raw material used for CBD extraction	
	CBD raw material manufacturing process chart	
	COA (raw materials/products) submitted at the time of import	
	Overseas Third Party COA	Optional
	Country of manufacture/manufacturer/manufacturing company information	
	Import Permit Notification	Sample available
	Notification of import of food, etc.	For food use
	Documents showing raw materials, pH, and temperature	for product inspection

	during product processing	
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**<Recommended domestic inspection>**

Our association recommends that inspections be conducted in Japan in order to ensure the quality of the services (are the amounts of ingredients contained in the services appropriate?). In particular, from the viewpoint of consumer protection, testing for CBD must not contain any gaps in the information regarding its ingredients, and we strongly recommend that it be analyzed in Japan. We also strongly recommend a thorough analysis (about twice a year). We also recommend analysis of other factors that affect quality (residues of pesticides, etc.).

The following is an example of the analysis content.

**CBD analysis content example**

<b>2. Regarding cannabinoid analysis contents</b>			Sample amount: 5g
Analysis type	Analysis item	Analysis result	LOD
Quantitative amount	CBD	% notation	10ppm
Qualitative	Total THC ( $\Delta 9/\Delta 8$ /THCA)	< 10 ppm	ND
Qualitative	$\Delta 9$ -THCP (designated drug)	< 10 ppm	ND
Measuring equipment:	Shimadzu high performance liquid chromatograph Nexera X2 (detection unit: SPD-20A)		
*	The above items are required for analysis, but are subject to change according to laws and regulations.		

**About quality inspection**

Item	Analysis items	Standards
1	Microbial test <general viable bacteria count>	3000cfu/g or less
2	Microbial test <coliform bacteria>	negative
3	Pesticide residue	
4	Heavy metals (lead)	5ppm or less
5	Arsenic	3ppm or less
6	Additives (heptane, hexane, ethanol, methanol)	

**<Disclosure of test results>**

Regarding test results obtained domestically, it is recommended that consumers provide information on their website, etc.

**4.Transparent information disclosure**



At the time of sale and service introductions, we make it easy for users to know about the risks to consumers that are expected to occur when using a service, precautions to be taken when using the service, and disclaimers as a service provider when selecting a service. We will clearly disclose any additional risks, precautions, or incidents that consumers should be aware of on our homepage, etc. as soon as they become known.

#### **5. Clarification of information handling methods**

When handling consumers' personal information when providing services and products, the information must comply with the Personal Information Protection Act and guidelines, such as clearly indicating the purpose of use, prohibiting use for other purposes, and dealing with information leaks and leaks. Establish a security system and clearly state its handling policy and operation method. (\*)

\*Laws and guidelines related to the Act on the Protection of Personal Information, including the Act on the Protection of Personal Information (Act No. 57 of May 30, 2003) and the Guidelines on the Act on the Protection of Personal Information (General Provisions). be compatible with

(Reference: Personal Information Protection Commission: <https://www.ppc.go.jp/personalinfo/legal/>)

#### **6. Clarification of target**

It must be clearly stated that the services and products provided are not drugs or medical devices, nor do they contain content that falls under medical practice. In addition, it must be clearly stated that this service is not intended for the diagnosis, treatment, or prevention of diseases, and those who require such activities are not the intended consumers.

#### **7. Clarification of operating entity and continuity**

In order for consumers to accurately understand the details of the company or organization that provides and operates the provided services and products, the information must be accurately stated in a place that can be easily checked on the service introduction homepage, etc. In addition, the rules for advance notices and notifications regarding the consumption period, warranty period, and termination of the service shall be clearly stated in the service terms and conditions, manuals, etc., and when the service is to be terminated, advance notices and notices to that effect shall be provided as promptly as possible in advance. and specify the response to consumers upon termination.

### **Chapter 3 : Addressing ethical, legal, and social issues**

#### **1. Consumer consultation desk**

Consumer consultation desks should establish ``consultation desks that are easy for everyone to access'' to receive consultations and complaints. In addition, if there is a consultation or complaint, promptly confirm the facts and take necessary measures. In response, we will prepare response manuals for each company, share information, and implement more effective preventive measures.

## **2.About education**

Provide other necessary information and provide education (\*) to deepen understanding so that employees working at the company are also aware of the guidelines. Also, it should be carried out regularly, not just the first time. If you are selling through an agent or retailer, make every effort to provide accurate information about your products and services by using flyers, homepages, etc. In addition, each company is responsible for supervising and educating tools (notices, etc.) used by agents and retailers to introduce their products and services.

(\*) The educational content includes not only the content of services and products provided to consumers, but also content related to corporate compliance such as related laws and regulations, national guidelines and guidelines, guidelines and guidelines of related academic societies, and various ethical and also includes legal and social issues and policies for responding to those issues.

## **3.Guidelines for dealing with anti-social forces**

Recognizing the importance of eliminating transactions with anti-social forces and preventing organized crime, etc., we will develop systems and environments to comply with applicable laws, regulations, etc. and government guidelines. Additionally, in order to ensure that appropriate measures are taken in a timely manner, we will provide guidance and training to each company to ensure that all companies are thoroughly informed about eliminating transactions with anti-social forces and preventing organized crime.

## **Chapter 4 : About appropriate advertising**

When advertising, businesses must comply with relevant laws and regulations to avoid advertising that is inconsistent with reality or that misleads consumers.

### **<Example of prohibited matters>**

- Expressions that indicate efficacy
- Exaggerated expression
- Superlative expression

(Example) "Highest", "Maximum", etc.

- Warranty expression

(Example) "Absolute", "100%", etc.

- Warranty expressions related to safety

(Example) "There is no danger" etc.

- Not linking products to evidence of effectiveness

(Example) "Show evidence of the effect on the body and explain the effect" etc.

- Expressions that promote the functions of body tissues, such as preventing or treating diseases.

(Example) "It cures..." "It works for..." "Product name that sounds like medicine", etc.

- Expressions that lead to diagnosis

(Example) "I understand ...", "I will judge the risk of ...", etc.

- Expressions that can improve sleep (quality)

(Example) “It will get better,” “It will work,” etc.

- Expression using user experience stories, etc.

(Example) "Letter of appreciation from a regular user", "I use it too", etc.

## **Chapter 5 : Review of guidelines**

The compliance status of business operators with the matters stipulated in the guidelines, the Act on Ensuring the Quality, Efficacy, and Safety of Pharmaceuticals and Medical Devices, etc. (Pharmaceutical Devices Act), the Personal Information Protection Act, the Act on Premiums and Representations, etc. Issuance and revision of relevant laws and regulations, related guidelines, etc., changes in consumer awareness and demand for personal information protection and services provided by business operators, and reexamination of the safety, prevention, and health effects of healthcare services. It shall be reviewed from time to time in response to changes in the social environment, such as the need for

## **Chapter 6 : Definition of words**

### **① CBD service and hemp-related service provider**

Represents not only our member companies but also all companies and intermediaries in the business of providing CBD services and hemp-related services.

### **② Evidence (test results)**

Indicate evaluations and results of products and services provided by business operators, such as effectiveness, quality, and safety.

## **Chapter 7 : Related Laws and Regulations**

Products and services provided by businesses must comply with relevant laws and regulations to ensure the physical safety of consumers and protect their interests.

Act on Ensuring the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, etc. (August 10, 1960, Ministry of Health, Labor and Welfare)

Medical Practitioners Act (July 30, 1948, Ministry of Health, Labor and Welfare)

Medical Law (July 30, 1948 Ministry of Health, Labor and Welfare)

Act on the Protection of Personal Information (May 30, 2003 Personal Information Protection Commission)

Food Sanitation Law (December 24, 1948, Ministry of Health, Labor and Welfare)

Health Promotion Act (August 2, 2002, Ministry of Health, Labor and Welfare)

Premiums and Representations Act (Act against Unjustifiable Premiums and Misleading Representations) (May 15, 1960 Consumer Affairs Agency)

Pharmaceutical Affairs Law (Act No. 145 of 1960, Ministry of Health, Labor and Welfare)

Act on Specified Commercial Transactions (Act No. 57 of 1976 Consumer Affairs Agency)

\*The above is an example and does not cover all the laws, etc. that should be considered. Also, refer to notices, guidelines, etc. related to laws, etc.

### **Reference standard**

- Privacy Mark system

(Personal information protection management system (Japan Information Economy and Society Promotion Association (JIPDEC))

- ISO9001 (quality management system),

• ISO10001 (Quality Management - Customer Satisfaction - Guidelines for Code of Conduct in Organizations)

• ISO10002 (Quality Management - Customer Satisfaction - Guidelines for Complaint Handling in Organizations)

(International Organization for Standardization (ISO))

- Foods with functional claims

- Food for specified health uses

(Consumer Affairs Agency)

\*The above is an example and does not cover all standards etc. that should be used as reference.