

Summary of Submitted Documents

These are the documents required for submission to the Ministry of Health, Labor, and Welfare. They include Declaration about raw materials, raw hemp stem photos, a certificate of analysis of raw materials, a manufacturing process chart for the final product, and a list of raw materials and additives for the final product.

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Declaration about raw materials

Required item

Please clearly state the following information and submit it on paper with your company logo if possible.

- Production area and farm name for raw material hemp
- The hemp raw material used is only mature stems (and seeds) of industrial hemp.

*Please be sure to use the term "mature stem" or "mature stalk". MHLW is particular about this.

Below is a sample of the declaration.

Dear Japanese Government,

We hereby declare that the CBD and other cannabinoids in our products are extracted from mature stems and seeds from industrial certified hemp under the supervision of The [State name] Department of Agriculture's Hemp Pilot Program.

This Hemp was organically grown using no pesticides. The hemp plants used to produce our CBD extracts have finished flowering stage and are therefore considered 'mature' plant.

Additionally, the extracts are derived from stems and seeds of the plant. Organic hemp material used for extraction is grown and cultivated without herbicides and pesticides.

The hemp plants are carefully selected, grown organically and hand harvested with utmost care under the supervision of The [State name] Department of Agriculture's Hemp Pilot Program in the [Farm name] hemp farm.

Sincerely,

[Your company name]

[address]

[Title/Responsible Person Name]

[Handwritten signature]

[date]

Raw Hemp Stem Photo

Accepted Samples



Includes examples of raw hemp stems meeting the required quality standards.

Raw Hemp Stem Photo

NG Samples

Shows raw hemp stems that do not meet the quality standards and are not suitable for use.



Reason: The photo is unclear. It appears that not only the main stem but also the branches are shown.



Reason: Cut too small.

Photo of Hemp Stalks Being Fed into a Grinder

Example Photos

Provides visual representation of the process of grinding hemp stalks, highlighting the equipment and the input materials.



Certificate of Analysis of Raw Materials

Required items	Identify the essential items that should be clearly presented in the analysis.
Inspection agency name/contact information	Details the name and contact information of the agency responsible for inspection.
Inspection manager title/name/signature/date	Demonstrates the details of the inspection manager's identification and the date of the inspection.
Inspection method	Explains the method used for the inspection of raw materials.
Cannabinoid detection value table (LOD description)	Displays the values for cannabinoid detection along with the limit of detection description.

Manufacturing Process Chart for Final Product

1

Start

Indicates the beginning of the manufacturing process.

2

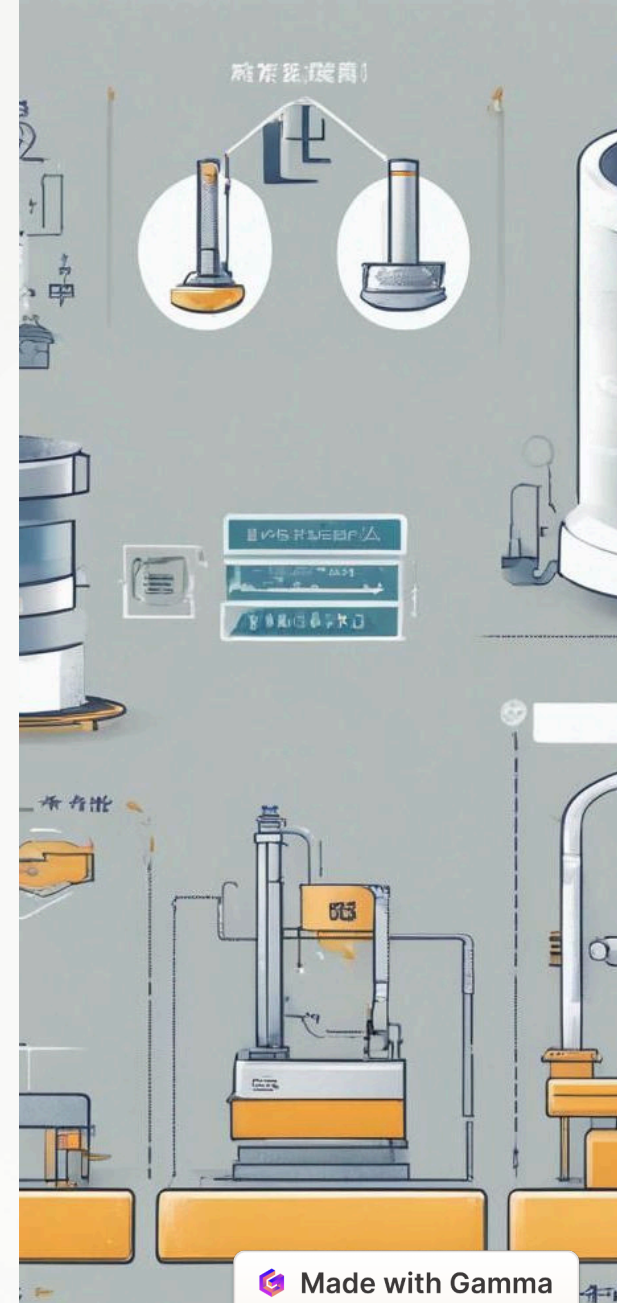
Processing

Illustrates the various steps involved in processing the raw materials.

3

Final Product

Shows the culmination of the process with the creation of the final product.



List of Raw Materials and Additives for Final Product

Legal Considerations

MHLW is particularly concerned with the source of cannabinoids and residual levels of THC. THC must be undetectable.

Restrictions

The analytical testing method should be one that is used worldwide. If a special method is described, MHLW may reject it. Japanese consumers generally prefer CO2 extraction methods.

Inspection Process

Although MHLW does not care, depending on the type of additives and synthetic colorants used in the product, the product may be inspected at the direction of the quarantine station upon arrival in Japan.



Response from MHLW

1 Communication Method

Documents are submitted by the importer to MHLW via email. They will not accept it any other way.

If the import is approved, you will receive a response by phone.

If it is NG, you will receive a reply via email.

2 Response Time

Currently, it takes more than two months to receive a response from MHLW after submitting the documents.

Unfortunately, they are good at finding very small bugs, so they often ask for something to be corrected in the first response.

3 Import Permission

Please ship the product after obtaining import permission from MHLW. A second shipment of the same product with the same batch number or lot number does not require MHLW permission. However, if the batch number or lot number is different, you will need to obtain another import permit from MHLW.

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