

THE COMMONWEALTH OF MASSACHUSETTS

EXECUTIVE OFFICE OF ENERGY AND ENVIRONMENTAL AFFAIRS



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2020 Hemp Processor Policy

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Program Application: Commercial Processors of Hemp

Approved By: John Lebeaux, Commissioner

Authority: M.G.L. c. 128, Sections 116 through 123

Policy Number: 2020-1

On July 28, 2017, Governor Baker signed H. 3818, An Act to Ensure Safe Access to Marijuana ("Act"), which updates the Commonwealth's laws that governs the use of marijuana. This legislation also created a distinction between marijuana, and Hemp, allowing Hemp to be grown commercially.

Through newly added Sections 116 through 123 of M.G.L. c. 128, the Massachusetts Department of Agricultural Resources ("Department") now has the authority to oversee Hemp within the Commonwealth of Massachusetts.

Purpose and Scope

This document sets forth the Department's updated Commercial Processor Policy ("Policy"). This Policy replaces the previous Interim Policy that was issued by the Department on April 30, 2018. All individuals seeking to participate in the processing of Hemp must comply with this Policy in order to be deemed in compliance with Massachusetts law.

The Department will consider all permitted activities under this Policy as falling under the definition of "Industrial Hemp" in M.G.L. c. 128, Section 116. All references to "Hemp" or "Industrial Hemp" in this Policy shall mean Industrial Hemp. The Policy establishes the Department's expectations related to the commercial processing of Industrial Hemp and provides information on how to become a licensed Processor. All proposed commercial activities related to the processing of Hemp require licensing in accordance with this Policy in order to be considered in compliance with M.G.L. c. 128, Sections 116 through 123. If there is a question as to whether a proposed activity requires a license under M.G.L. c. 128, Section 118, please contact the Department to determine whether the activity falls under this Policy.

Under M.G.L. c. 128, Sections 116 through 123, processing Hemp for commercial purposes in Massachusetts falls under the jurisdiction of MDAR and requires licensing by MDAR.

Other State and Federal Agencies

Please note, with the passing of the 2018 Farm Bill, Hemp is now considered an agricultural commodity and the cultivation of Hemp is under the jurisdiction of the United States Department of Agriculture ("USDA"). The United States Food and Drug Administration ("FDA") also has jurisdiction over Hemp under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and other related laws from a public health perspective. The FDA has issued a statement

which can be found at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635048.html>, puts limitations on the types of cannabis-derived (including Hemp derived) products that may be manufactured and sold, in particular products containing the cannabinoid known as “CBD.”

In addition, the Massachusetts Department of Public Health (“DPH”) has issued FAQs which can be found at: <https://www.mass.gov/info-details/cbd-in-food-manufactured-or-sold-in-massachusetts>. The DPH FAQs are consistent with the FDA statement, and local boards of health have the authority to enforce public health laws and regulations within a municipality.

Should additional changes be made by the state or federal government, the Department will update all licensees. Please also make sure to review all applicable statutes, regulations, or guidance issued by the United States Food and Drug Administration (“FDA”) and any other applicable requirements that may apply to what you are producing, especially if those products contain CBD or are marketed for CBD purposes.

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Key Considerations

As noted above, while M.G.L. c. 128, Sections 116 through 123 authorize certain activities related to Hemp in the Commonwealth, such activities may be subject to other state and federal limitations.

- The USDA Final Interim Rule on Hemp Production applies only to the *production or cultivation* of Hemp plants for market.¹ MDAR’s requirements related to *processing* are derived from its authority set forth in M.G.L. c. 128, Section 116 through 123.
- While the Department has jurisdiction to license the processing of Hemp, other local, state or federal agencies may also have requirements that apply to your business. All Hemp processors should carefully review local bylaws, ordinances, and other municipal, state, and federal requirements in order to ensure compliance. Failure to maintain compliance with other applicable laws may result in the loss of your processor license.
- As an entity that would like to process Hemp, it is important for you to:
 - Review the products that are allowed for sale in Massachusetts as this might impact your business plan.
 - Review the testing requirements, as some testing may need to be conducted during the cultivation period. Processors will need to coordinate with Growers in order to ensure compliance with the testing requirements.

¹ <https://www.ams.usda.gov/rules-regulations/hemp>

- Review all applicable statutes, regulations, or guidance issued by the FDA and any other applicable requirements that may apply to what you are producing, especially if those products contain CBD or are marketed for CBD purposes. This also includes understanding any limitations on any products that have been imposed by FDA, DPH and your local board of health.
- Review the policy relative to the sale of products in Massachusetts that contain CBD.²
- The Department does not allow raw plant material to be packaged, labeled and made ready for sale to the end consumer. Raw plant material includes but is not limited to the following:
 - Flower
 - Whole Plant
 - Leaves
- Regardless of the change in federal law, property that is subject to an Agricultural Preservation Restriction (“APR”) or and Agricultural Covenant with the Department is not currently eligible to participate in the Hemp Program until such time as the definition of horticulture in M.G.L. c. 61A, Section 2 is clarified by the Legislature.

I. GENERAL INFORMATION

A. Definitions

As used in this Policy, the following words shall have the following meanings:

Cannabidiol or CBD: One of the several compounds produced by cannabis plants that have medical effects.

Cannabinoids: Any of several compounds produced by cannabis plants that have medical and psychotropic effects. This includes but is not limited to CBD and THC.

Cannabinoid profile: The amounts expressed as the dry weight percentages, of delta-nine-tetrahydrocannabinol, Cannabidiol, tetrahydrocannabinolic acid and cannabidiolic acid in a Hemp product.

Hemp Certificate: Documentation stating that the Department has sampled and tested the Crop and determined that the Crop demonstrates that it is at 0.3% THC or below.

Commercial: Processing Hemp for market.

Crop: Any plant(s) grown for the purposes of being Hemp.

Department: Massachusetts Department of Agricultural Resources.

Extractor: A Processor that creates Hemp products directly from the Hemp plant. The Extractor will produce items such as fiber, seed, or oil from the plant.

Grower: A person that cultivates Hemp.

² <https://www.mass.gov/info-details/faqs-sale-of-hemp-derived-products-in-the-commonwealth>

Hemp: The plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.30 percent on a dry weight basis as defined by the Agricultural Improvement Act of 2018, Pub.L. 115-334, as amended.

Manufacturer: A Processor that creates an end product that is packaged, labeled and ready for sale from Hemp including but not limited to cloth, infused products, or building products.

Person: A natural person, corporation, association, partnership or other legal entity.

Processor: A person that converts Hemp into a marketable form. A Processor may be either an Extractor, a Manufacturer or both.

Produce or Production: To grow Hemp plants for market, or for cultivation for market, in the United States.

Producer: A person who produces Hemp.

Licensee: The holder of a License from the Department.

License: Authorization that is provided by the Department to the Licensee following the review and approval of an application containing the required information.

Retail: The offering of goods or services to a consumer for profit. For the purposes of this policy, Retail shall not include the sale of Hemp when such sale takes place exclusively between a Grower, Grower/Processor, or Processor licensed by the Department pursuant to M.G.L. c. 128, Section 118.

THC: Delta-9-tetrahydrocannabinol.

THCa: Tetrahydrocannabinolic acid, which converts to THC when decarboxylated.

Total THC: means the total available THC as measured after decarboxylation or derived from the sum of the THC and THCa content using the following formula: $\text{delta-9 THC} + (\text{THCa} * 0.877)$.

B. Hemp Products for sale in Massachusetts

Before becoming a processor in Massachusetts, it is very important to understand what products are allowed for sale in Massachusetts as this may dictate what a Processor decides to extract or manufacture. Below is a list of products that are allowed and not allowed pursuant to M.G.L. c. 128, Section 117(c) and under FDA and DPH guidance:

Approved Hemp Products that are allowed for sale in Massachusetts

- Hemp seed
- Hemp seed oil
- Hulled Hemp
- Hemp seed powder
- Hemp protein
- Clothing
- Building material
- Items made from Hemp fiber
- Flower from a Massachusetts licensed Grower to another Massachusetts licensed Grower or Processor

Pursuant to the Massachusetts Department of Public Health and as set forth in the Sale of Hemp-Derived Policy issued by the Department on June 12, 2019, the following Hemp Products are prohibited for sale in Massachusetts:

- Food containing CBD derived from Hemp;
- Any product containing CBD derived from Hemp that makes therapeutic/medicinal claims;
- Any product that contains Hemp as dietary supplement;
- Animal feed that contains any Hemp products;³
- Unprocessed or raw plant material, including the flower.

C. Application Requirements and Process for a Licensed Hemp Processor

Any Person proposing to engage in the processing of Hemp must obtain a license issued by the Department, depending on the type of activity.

1. Licenses are required for Processors prior to engaging in any activity authorized by M.G.L. c. 128, Sections 118 through 123 or this Policy. A Processor is separated into two different categories: Extractor; and/or Manufacturer. Each applicant for a Commercial Hemp Processor license shall submit to the Department a complete application, which includes the following information:
 - i. Full name and address of applicant(s);
 - ii. Name and address of the Hemp operation;
 - iii. GPS coordinates provided in decimal degrees taken at the approximate center of the building entrance; A map of the processing area illustrating clear boundaries;
 - iv. Written consent by the applicant to the Department to conduct inspections, sampling, and testing under the terms of this policy;
 - v. A non-refundable application fee in an amount which shall be established by the commissioner and;
 - vi. Any other information reasonably requested by the Department to fulfill its oversight obligations pursuant to M.G.L. c. 128, Sections 118 through 123.

Applications are available at the following website: <https://www.mass.gov/how-to/ma-industrial-hemp-program-licensing>. In addition to the application form, each applicant shall submit a nonrefundable application fee. If the application fee does not accompany the application, the license application will be deemed incomplete and will not be processed until such time as the fee is received. If an application is approved, an additional license fee shall also be required prior to issuance of Processor license. All licenses will expire on December 31st of the year it was issued.

Upon the approval of an application for a Processor license, the Department will notify the state and local police as well as local fire department in the municipality where the Hemp will be processed. This notification will include the address and GPS coordinates of the processing facility. The Department will also notify the chief administrative or executive officer⁴ in the municipality where Hemp will be processed in order to answer any

³ See,

<https://www.aafco.org/Portals/0/SiteContent/Announcements/Guidelines on Hemp in Animal Food May 1 2019.pdf>.

⁴ “Chief administrative officer,” when used in connection with the operation of municipal governments, shall include the mayor of a city and the board of selectmen in a town unless some other local office is designated to be the chief administrative officer under the provisions of a local charter... ‘Chief executive officer’, when used in connection with the operation of municipal governments shall include the mayor in a city and the board of selectmen in a town unless some other municipal office is designated to be the chief executive officer under the provisions of a local charter.” See M.G.L. c. 4, Section 7.

questions or concern that they may have. The licensee’s address and security schematic or global positioning system coordinates that are provided to the chief administrator/executive offer, police, and fire shall not be subject to public disclosure as set forth in M.G.L. c 128, Section 118 and any transmittal of this information from the Department shall include the fact that it is exempt from public disclosure by statute.

2. Grower/Processor Dual License: A Person proposing to participate in growing and processing activities may apply for a Grower/Processor license and fill out the appropriate application form and submit the appropriate application and license fees. Anyone applying for a Dual Grower/Processor license will be required to follow both the 2020 Hemp Processor Policy and the Hemp Producer Regulations.

Fee Schedule applicable to Processor Licenses⁵

License Type	Application Fee	License Fee
Processor (Extractor, Manufacturer or both)	\$100 non-refundable (annual)	\$300 (annual)
Grower	\$100 non-refundable (annual)	\$300 (annual)
Dual Grower & Processor	\$100 non-refundable (annual)	\$500 (annual)

3. Approval/Denial of License Application; Renewal

Pursuant to M.G.L. c. 128, Section 119, the Department shall grant or deny a license application after reviewing and ensuring all statutory and Policy requirements have been met. Any applicant denied a license or license renewal may appeal no later than twenty-one (21) days after receipt of the notice of the licensure action pursuant to M.G.L. c. 128, section 123. A request for an appeal should be submitted in writing to the Department. An adjudicatory hearing shall be conducted in accordance of M.G.L. c. 30A.

4. Approval

If approved, the Department may issue a license that will contain, at a minimum, the following:

- Full name and address of the applicant(s);
- Name and address of the Hemp operation;
- Department issued license number;
- Signature of Department representative;
- A written finding that the Processor has complied with M.G.L. c. 128, Section 116-123 and licensure is in the best interest of the Commonwealth; and
- Expiration date (all licenses will expire on December 31st of the year issued).

In the event of any change to the information provided to the Department in the license application, including the growing location, the Licensee shall immediately notify the Department. Once notified, the Department will review the change to determine whether a new license application or an amendment to an existing license will be required. A licensee shall not implement any proposed changes without prior written approval from the Department.

5. Denial

Pursuant to M.G.L. c. 128, Section 119(b), the Department “shall deny an application for a license filed pursuant to section 118 if the applicant: (i) fails to satisfy the minimum qualifications for licensure pursuant to sections 116 to 123, inclusive; or (ii) for good cause shown.” Good cause to deny an application

⁵ These fees will be promulgated as part of 801 C.M.R. 4.00, in consultation with the Executive Office for Administration and Finance. Until further notice, applicants shall pay the fees listed above.

may include, but not be limited to the following: failure to comply with this Policy or other statutes or regulations that govern the operation, problematic site location, or failure to provide additional information reasonably requested by the Department.

6. Renewal

All Processors will be required to submit a license renewal application prior to the expiration date of their current license. In order to ensure that the Department has ample time to review and issue the renewal, renewal applications must be submitted to the Department between October 1st and December 31st. The Department will review all renewal applications in accordance, with M.G.L. c. 128, Sections 116 through 123 and all regulations, policies, and guidance that may be in effect at the time the renewal application is submitted. The Department will also evaluate the Processor's previous activities as a Processor. The Department may deny a renewal under the Section 119(b) if it determines the Processor has not complied with this Policy or other statutes or regulations that govern the operation.

D. Land Use Restrictions for Licensed Processors

- Property that is subject to an Agricultural Preservation Restriction ("APR") is not currently eligible to participate in the Hemp Program until such time as M.G.L. c. 61A, Section 2 is clarified by the Legislature.
- If the total number of acres you intend to use to grow or process your Crop is less than two (2) acres, you may not be afforded any zoning enforcement protections afforded to commercial agricultural activities under M.G.L. c. 40A, Section 3. All activities are subject to local zoning, subject to M.G.L. c. 40A, Section 3.

II. PROCESSOR INFORMATION

Processors are divided into two different categories based upon their activities:

- **Extractor:** Processor that creates Hemp products directly from the plant. The Extractor will produce items such as fiber, seed, and oil from the plant.
- **Manufacturer:** Processor that creates a Hemp-derived end product that is packaged, labeled and ready for sale including but not limited to cloth, infused products and building products.

It is the responsibility of the Processor to understand any limitations on the types of products for which Hemp may be used. This includes understanding both the processing, labeling, and marketing requirements and any applicable limitations through a careful review of all applicable statutes, regulations, or guidance issued by the FDA and any other applicable requirements that may apply, especially if those products contain CBD or are marketed for CBD purposes. This also includes understanding any limitations on any products that have been imposed by the local board of health.

It is the responsibility of the Processor to ensure that any testing requirements that are required to be done prior to or during the cultivation period have been conducted. The Processor will need to communicate and coordinate with the Grower to ensure the testing has been completed.

There are different duties and responsibilities as described below depending on the type of Processor activity. A Processor can be both an Extractor and a Manufacturer.

1. Duties and Responsibilities of the Extractor:

- a. Any Hemp or Hemp-derived product used for processing shall only be obtained from a Producer licensed by the Department, USDA, under a USDA-approved plan from a jurisdiction outside the Commonwealth, or as otherwise authorized under federal law relating to the importation of Hemp and accompanied by all the required paperwork. Hemp may not be

obtained from any jurisdiction within the United States that does not have a USDA-approved plan unless the Hemp was produced under a USDA-issued license.

- b. An Extractor must ensure that the Hemp received for processing complies with the testing requirements set forth by the Department, including that it meets all contaminant limitations, along with any other applicable testing requirements or standards set by local, state, or federal law for the type of product to be produced.
- c. At the time of receipt, the Extractor must assign the Crop a lot number that corresponds with Grower information such as name, address, contact information and maintain records relative to the receipt of the Crop.
- d. An Extractor shall keep records for all Hemp obtained. The records shall be kept for a minimum of three (3) years and shall include, but not be limited to:
 - i. Date of receipt
 - ii. Quantity of Hemp received
 - iii. Grower information, including name, location, license information and contact information.
 - iv. Copy of the Hemp Producer License issued by the Department, USDA, or under a USDA state-approved plan from a jurisdiction outside the Commonwealth.
 - v. Lot number assigned by Extractor
 - vi. Lab reports demonstrating that the Hemp to be processed contains less than 0.3% total THC, has met all contaminant limitations, and any other testing requirements or standards set by local state or federal law.
- e. An Extractor shall keep records for each batch processed. The records shall be kept for a minimum of three (3) years and shall include, but not be limited to:
 - i. Date of extraction
 - ii. Batch number, including the lot number
 - iii. Extraction method used
 - iv. Amount extracted
 - v. What raw material was used for the extraction (grain, seed, fiber, oil, flower)
 - vi. Lab testing results

2. Duties and Responsibilities of the Manufacturer

- a. Any Hemp or Hemp-derived product used for processing shall only be obtained from a Producer licensed by the Department, USDA, under a USDA-approved plan from a jurisdiction outside the Commonwealth, or as otherwise authorized under federal law relating to the importation of Hemp and accompanied by all the required paperwork. Hemp may not be obtained from any jurisdiction within the United States that does not have a USDA-approved plan unless the Hemp was produced under a USDA-issued license.
- a. At the time of the receipt, the Manufacturer shall assign the extracted product a lot number and maintain records relative to the receipt of the extracted product. The records shall be kept for a minimum of three (3) years and include, but not be limited to:
 - i. Date of receipt
 - ii. Amount received
 - iii. Extractor and/or Grower information including name, license number, and contact information, and copy of the Hemp Producer License issued by the Department, USDA, or under a USDA state-approved plan from a jurisdiction outside the Commonwealth.

- iv. Lab results.
 - v. Lab reports demonstrating that manufactured product contains less than 0.3% total THC, has met all contaminant limitations, and any other testing requirements or standards set by local state or federal law.
 - vi. Extractor assigned batch and lot number
- b. When the Manufacturer produces an end product, records shall be kept for a minimum for three (3) years for each batch of the end product. The records shall include, but not be limited to:
- i. Date of production
 - ii. Batch number (must include lot number)
 - iii. Amount produced
 - iv. Name of product
3. Labeling Requirements for the Manufacturer
- a. Manufacturers shall ensure that any products that will be used for human consumption and absorption (including but not limited to inhaling, swallowing or topical application), are labeled in clear, legible wording no less than 1/16 inch in size on each container.
 - b. Labels shall be firmly affixed and shall include the following:
 - i. Manufacturer name, license number and address
 - ii. Cannabinoid profile (Must include THC and CBD concentrations, if any)
 - iii. Batch number
 - iv. Statement *“This product derived from Hemp has not been tested, analyzed, or approved by the Massachusetts Department of Agricultural Resources or the FDA.”*

V. Testing Requirements

The Department is utilizing the same testing requirements as the Cannabis Control Commission (“CCC”) for Hemp-derived products. While the CCC does not have jurisdiction over Hemp and will have no role in the testing of Hemp or Hemp-derived products, Hemp Processors must have products tested according to the *Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products*. These testing protocols are available on the website at <https://www.mass.gov/info-details/medical-use-of-marijuana-program-product-testing#cannabis-control-commission-testing-protocols>. If test results exceed the limits set forth in the Testing Guidelines for heavy metal, biological, solvents (if used), or cannabinoids then the Department must be notified. Failure to notify the Department may result in the loss of your license. Testing for pesticide residue is not required at this time.

IV. Enforcement

The Department will make every effort to work with Processors to provide compliance assistance. However, it is the responsibility of the Processor to review and understand M.G.L. c. 128, Sections 116 through 123 and this Policy. Failure to comply with the Department’s requirements under this Policy may result in the need for corrective action up to the revocation or denial of a license. An entity has the right to appeal any enforcement action under M.G.L. c. 128, Section 123.

The Department will determine the appropriate action based on the nature of the violation, and considering all relevant factors including the ability for the violation to be corrected, severity of the violation, willfulness, impact to public health and safety.