

# THE COMMONWEALTH OF MASSACHUSETTS

EXECUTIVE OFFICE OF ENERGY AND ENVIRONMENTAL AFFAIRS



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## **2024 Hemp Processor Policy**

**Effective Date:** April 3, 2024

**Program Application:** Commercial Processors of Hemp

**Approved By:** Ashley E. Randle, Commissioner

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

**Policy Number:** 2024-1 (Updates and replaces Policy 2022-1)

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.

As a result of the Act, and pursuant to sections 116 through 123 of M.G.L. c. 128, the Massachusetts Department of Agricultural Resources (“MDAR”) has the authority to oversee hemp, including the processing of hemp and hemp-derived products, within the Commonwealth of Massachusetts.

This Policy updates and replaces the 2022 Hemp Processor Policy.

### **Purpose and Scope**

This document sets forth MDAR’s updated Commercial Processor Policy (“Policy”). This Policy replaces the previous Hemp Processor Policy that was last updated on October 17, 2022. All individuals and entities seeking to participate in the processing of hemp must comply with this Policy in order to be deemed in compliance with Massachusetts law.

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. MDAR will consider all authorized activities under this Policy as falling under the definitions of “Industrial Hemp” or “Hemp” in M.G.L. c. 128, Section 116. All references to “Hemp” in this Policy shall include industrial hemp and hemp, where applicable. The Policy establishes MDAR’s expectations related to the commercial processing of 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, unless otherwise exempt from licensing under this Policy. If there is a question as to whether a proposed activity requires a License under M.G.L. c. 128, Section 118, please contact MDAR to determine whether the activity falls under this Policy.

### *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 regulations which can be found at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>, puts limitations on the types of cannabis-derived (including hemp-derived) products that may be manufactured and sold, in particular products containing the cannabinoids known as “CBD” as well as delta-9 THC.

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. Questions regarding the manufacturing of food products in the Commonwealth should be directed to DPH’s Food Protection Program.

Should additional changes be made by the state or federal government, MDAR will make every effort to update all Licensees. Please 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 THC or are marketed for CBD or THC 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.<sup>1</sup> MDAR’s requirements related to *processing* are derived from its authority set forth in M.G.L. c. 128, Section 116 through 123.
- While MDAR has jurisdiction to license the processing of Hemp, other local, state or federal agencies may also have requirements that apply to Hemp processors. These local, state and federal agencies

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

include, but may not be limited to, the following:

- FDA
- DEA
- Department of Public Health
- Local Boards of Health
- Alcohol and Beverage Control Commission
- Local Fire Department
- Cannabis Control Commission

This list is not intended to be exhaustive; it is the responsibility of the Licensee to ensure they are in compliance with all applicable requirements and obtain all necessary permits, approvals, and licenses in addition to those required by MDAR.

- All Hemp processors should carefully review local bylaws, ordinances, and other municipal, state, and federal requirements to ensure compliance. Failure to maintain compliance with other applicable laws may result in the loss of your Processor License. This includes, but is not limited to, board of health requirements, zoning requirements, and building and fire codes.
- It is important for any entity that would like to Process Hemp to:
  - Review the products that are allowed for manufacture or 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 Producers in order to ensure compliance with the testing requirements.
  - 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 THC or are marketed for CBD or THC purposes. This also includes understanding any limitations on any products that have been imposed by FDA, DPH and your local board of health.
  - Review all policies relative to the sale of hemp and hemp-derived products in Massachusetts that contain CBD or THC.<sup>2</sup>
- MDAR does not allow raw plant material to be packaged, labeled, and made ready for sale to the end consumer except to a Person Licensed by the Cannabis Control Commission (“CCC”) for sale in a marijuana establishment and in accordance with any guidance or regulation promulgated by the CCC as authorized by M.G.L. c. 94G, Sections 4 and 12.<sup>3</sup> Raw plant material includes but is not limited to: the following:
  - Flower
  - Whole Plant
  - Leaves
  - Pre-rolled/Packaged Hemp for Smoking
- Industrial hemp Processing facilities shall maintain physical and operational separation from any marijuana-related facility. If the facility is located in the same building or on the same site or property as a marijuana facility access must be completely separated from the marijuana facility which includes but is not limited to separate entrances and exits. MDAR reserves the right to request additional information at the time of application to ensure licensing would be in the best interest of the

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<sup>2</sup> <https://www.mass.gov/policy-statement/sale-of-hemp-derived-products-in-the-commonwealth>

<sup>3</sup> <https://masscannabiscontrol.com/wp-content/uploads/2022/01/Guidance-on-Hemp.pdf>

Commonwealth. MDAR will also coordinate with the CCC whenever necessary to ensure any cross-jurisdictional issues are addressed.

## I. GENERAL INFORMATION

### A. Definitions

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

Batch: A quantity of hemp or hemp-derived material processed in one operation or in one continuous or semicontinuous process or cycle.

Batch Identification Number: A unique, sequential number that is assigned to each batch and corresponds to a Lot and identifies the source of the material acquired, and the date of acquisition.

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

Cannabinoid: 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 other Cannabinoids in a Hemp product.

CCC: Cannabis Control Commission for the Commonwealth of Massachusetts as established by Chapter 55 of the Acts of 2017.

Certificate of Analysis: A certified report from a state Department of Agriculture, USDA as allowed by 7 CFR Part 990, or an Independent Testing Laboratory that summarizes all analytical testing and results performed on the hemp, extract, and/or product.

Commercial: Processing Hemp for market.

Commonwealth: Commonwealth of Massachusetts.

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

DPH: The Massachusetts Department of Public Health.

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.

Finished Product: A hemp product to be used without further processing that is packaged, labeled, and intended for sale.

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.<sup>4</sup>

Hemp Extract: A product other than hemp itself, which contains or is derived from hemp. Hemp Extracts may be in dry, liquid, or semisolid form, and may be obtained through use of solvents or physical processes and may include “concentrates,” “distillates,” “isolates,” “infusions,” “juices,” “oils,” “resins,” or “rosins” etc. Hemp Extracts of any type do not include synthesized cannabinoids such as delta-8 THC.

Independent Testing Laboratory: A laboratory that is licensed or registered by the CCC and is: (a) Currently and validly licensed by the CCC; (b) Accredited to ISO 17025:2017 or the International Organization for Standardization 17025 by a third-party accrediting body that is a signatory to the International Laboratory Accreditation Accrediting Cooperation mutual recognition arrangement or that is otherwise approved by the Commission; (c) Independent financially from any MTC Marijuana Establishment or Licensee; and 6 (d) Qualified to test Marijuana and Marijuana Products, including MIPs, in compliance with M.G.L. c. 94C, § 34; M.G.L. c. 94G, § 15; 935 CMR 500.000; and 935 CMR 501.000: Medical Use of Marijuana; and CCC protocol(s).

Licensee: The holder of a License from MDAR.

Lot: A quantity of hemp, by-products, extract, or seeds acquired on the same date from the same source.

Lot Identification Number: A unique, sequential number that is assigned to each Lot and corresponds to a record identifying the source of the material acquired, and the date of acquisition.

Manufacturer: A Processor that creates a Finished Product that is packaged, labeled and ready for sale from Hemp including but not limited to infused products, balms, or lotions.

MDAR: Massachusetts Department of Agricultural Resources.

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.

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 Producer, Dual Producer/Processor, or Processor Licensed by MDAR pursuant to M.G.L. c. 128, Section 118.

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<sup>4</sup> The 2018 Farm Bill defines “hemp” and while it allows states to be more stringent, it expressly provides that state laws cannot conflict. As a result, MDAR applies the federal definition of hemp when necessary to ensure compliance with state and federal law.

Synthetic Cannabinoid: A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring Hemp or other hemp-derived Cannabinoids.

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. Approved Hemp Products for Massachusetts Processors**

Before becoming a Processor in Massachusetts, it is very important to understand what products you are allowed to manufacture in accordance with state and federal law. Below is a list of products that are approved for manufacturing in the Commonwealth:

- Hemp seed
- Hemp seed oil
- Hulled Hemp
- Hemp seed powder
- Hemp protein
- Clothing
- Building material
- Items made from Hemp fiber
- Non-food CBD products for human consumption that do not make any medicinal/therapeutic claims on the label and are not marketed as a dietary supplement.
- Flower from a Massachusetts Licensed Producer to another Massachusetts Licensed Producer or Processor
- Packaged and labeled hemp flower or plant material sold to a Person licensed by the CCC and in accordance with any guidance or regulation promulgated by the CCC as authorized by M.G.L. c. 94G, Section 12
- Hemp-derived products as allowed above and sold to a Person licensed by the CCC and in accordance with any guidance or regulation promulgated by the CCC as authorized by M.G.L. c. 94G, Section 12
- Hemp-derived CBD extract or distillate sold to a Person licensed by the CCC and in accordance with any guidance or regulation promulgated by the CCC as authorized by M.G.L. c. 94G, Section 12
- Other reasonable Commercial purposes approved in advance by MDAR as consistent with the purposes of M.G.L. c. 128, Sections 116 through 123

Please note that while MDAR may not regulate a particular product, the manufacturing of such in the Commonwealth may not be permitted by other applicable state law, including but not limited to, DPH regulations. It is the sole responsibility of the Licensee to ensure compliance with all applicable state and federal laws at all times.

### **C. Prohibited Hemp Products in Massachusetts**

Pursuant to FDA, DPH, and as set forth in the Sale of Hemp-Derived Policy issued by MDAR on June 12, 2019, the following Hemp Products are prohibited in Massachusetts, regardless of where the product was Produced or Processed (i.e., includes products that do not originate from the Commonwealth):

- Food containing CBD or THC derived from Hemp;
- Any product containing CBD or THC derived from Hemp that makes therapeutic/medicinal claims;
- Any product that contains Hemp as dietary supplement;
- Animal feed that contains any Hemp products;<sup>5</sup>
- Unprocessed or raw plant material, including the flower, that is meant for end use by a consumer except when sold to a Person licensed by the CCC and in accordance with any guidance or regulation promulgated by the CCC as authorized by M.G.L. c. 94G, Section 12.
- Products containing any THC, including all isomers of THC with a concentration that exceeds 0.3%, and not otherwise authorized by state or federal law. Any synthetically derived THC including, but not limited to delta-8 THC, THCO, THC10, HHO, THC-o-acetate, which are not included in the definition of Hemp under state or federal law.
- Any ingredient MDAR determines would render the product injurious or hazardous to health.

### **D. Application Requirements and Process for a Licensed Hemp Processor**

Any Person proposing to engage in the Processing of Hemp within the Commonwealth must obtain a License issued by MDAR.

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. Each applicant for a Hemp Processor License shall submit to MDAR 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 MDAR 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 MDAR to fulfill its oversight obligations pursuant to M.G.L. c. 128, Sections 118 through 123.

Hemp Licenses are not transferrable or assignable and cannot be used by any other individual or entity than the Licensee.

Applications are made available during the open application period from December 1<sup>st</sup> to April 30<sup>th</sup> annually at the following website: [www.mass.gov/how-to/ma-industrial-hemp-program-licensing](http://www.mass.gov/how-to/ma-industrial-hemp-program-licensing). All Licenses expire on December 31<sup>st</sup> in the year of issue.

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<sup>5</sup> <https://www.aafco.org/Portals/0/SiteContent/Announcements/Guidelines on Hemp in Animal Food May 1 2019.pdf>.

Upon the approval of an application for a Processor License, MDAR 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. MDAR will also notify the chief administrative or executive officer<sup>6</sup> in the municipality where Hemp will be processed in order to answer any 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 MDAR shall include the fact that it is exempt from public disclosure by statute.

**2. Producer/Processor Dual License**

A Person proposing to participate in growing and processing activities may apply for a Dual Producer/Processor License and fill out the appropriate application form and submit the appropriate application and License fees. Anyone applying for a Dual Producer/Processor License will be required to follow both this Policy and the Hemp Production Regulations promulgated at [330 CMR 32.00](#).

**3. Licensing Fees**

Each applicant for an MDAR Hemp License shall submit a nonrefundable application fee as required by M.G.L. c. 128, Section 118. 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 the License.

Fee Schedule applicable to MDAR Hemp Licenses

License Type	Application Fee	License Fee
Processor	\$100 non-refundable (annual)	\$300 (annual)
Producer	\$100 non-refundable (annual)	\$300 (annual)
Dual Producer/Processor	\$100 non-refundable (annual)	\$500 (annual)

**4. Approval/Denial of License Application; Renewal**

Pursuant to M.G.L. c. 128, Section 119, MDAR 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 MDAR. An adjudicatory hearing shall be conducted in accordance with M.G.L. c. 30A and 801 CMR 1.02.

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<sup>6</sup> “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.



## **5. License Approval**

If approved, MDAR 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;
- MDAR issued License number;
- Signature of MDAR 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 31<sup>st</sup> of the year issued).

In the event of any change to the information provided to MDAR in the License application, including the processing location, the Licensee shall immediately notify MDAR. Once notified, MDAR 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 changes without prior written approval from MDAR.

## **6. License Denial**

Pursuant to M.G.L. c. 128, Section 119(b), MDAR “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 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 MDAR.

## **7. License 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 MDAR has ample time to review and issue the renewal, renewal applications must be submitted to MDAR between October 1<sup>st</sup> and December 1<sup>st</sup>. MDAR 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. MDAR will also evaluate the Processor’s previous activities as a Processor. MDAR 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.

## **8. Licensing Exemptions**

Entities that are solely selling hemp products and/or applying a label and brand name to an already Finished Product without manufacturing or otherwise processing any part of the product, handling, or altering the product within the Commonwealth are not required to obtain a License from MDAR at this time.

Entities licensed through the CCC who use Hemp as an ingredient in the production of a marijuana infused products in accordance CCC guidance are not required to obtain a processor License at this time. If a CCC Licensee wants to manufacture Finished Products that are packaged and labeled as hemp or hemp-derived, they must also obtain a MA Hemp Processor License from MDAR and ensure compliance with this Policy.

## **E. Land Use Restrictions for Licensed Processors**

- Property that is subject to an Agricultural Preservation Restriction (“APR”) may be eligible to participate in the Hemp Program, provided such participation will still result in compliance with all applicable terms of the APR. Please review the following guidance issued by MDAR for more [information](https://www.mass.gov/info-details/hemp-and-marijuana-production-on-apr-and-farm-viability-protected-lands) (<https://www.mass.gov/info-details/hemp-and-marijuana-production-on-apr-and-farm-viability-protected-lands>).
- 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. It is the responsibility of each applicant to understand and determine whether such activity will be in compliance with local zoning requirements.
- It is the responsibility of each applicant to understand and determine whether any other federal, state, or local approvals may be needed, including but not limited to, building permits or other approvals necessary for the type of processing proposed. It is also the responsibility of each applicant to understand applicable fire code requirements and ensure compliance at all times. Questions related to building and fire codes may be directed to your local building and fire department.
- All hemp processing must be in compliance with all applicable fire and building codes. MDAR may consider whether licensing in a residential dwelling is in the best interest of the Commonwealth based on factors including but not limited to, access for compliance requirements, safety to the surrounding area (both inside and outside the dwelling), and any other factors identified during a pre-licensing site inspection.<sup>7</sup>

## **II. PROCESSOR INFORMATION**

There are different duties and responsibilities for Licensed Hemp Processors as described below depending on the type of products manufactured.

### **1. Manufacture of Hemp Extracts**

- (a) Any Hemp used for extraction shall only be obtained from a Person Licensed by MDAR, 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.
- (b) Every Lot of raw Hemp acquired for use in processing must be accompanied by a Certificate of Analysis from the Licensed Producer indicating that it was certified by MDAR, USDA, under a USDA-approved plan from a jurisdiction outside the Commonwealth, or as otherwise authorized under federal law and passed all regulatory THC testing requirements.
- (c) At the time of receipt, the Processor shall assign the Hemp a Lot Identification Number and maintain records relative to the receipt of the raw material used for extraction. The records shall be kept for a minimum of three (3) years and include, but not be limited to:
  - i. Date of receipt.
  - ii. Quantity of Hemp received.

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<sup>7</sup> <https://www.mass.gov/doc/cannabis-fire-safety/download>

- iii. Source information, including location of origin for the Hemp and name, License, and contact information for the Hemp Producer from whom the Hemp was obtained.
  - iv. Lot Identification Number assigned by Processor.
  - v. Certificate of Analysis demonstrating the hemp was certified by MDAR, USDA, under a USDA-approved plan from a jurisdiction outside the Commonwealth, or as otherwise authorized under federal law and has passed regulatory THC testing requirements.
- (d) Hemp Extracts manufactured by a Processor must be assigned a unique Batch Identification Number. The Batch Identification Number should reference the Lot Identification Number such that a Hemp Extract can be traced back to its origin.
- (e) For every Batch of Hemp Extract manufactured by a Processor, representative samples must be submitted to an Independent Testing Laboratory for testing potency and contaminants in accordance with the [Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products](#) ("Protocol"). Certificates of Analysis should be provided by the Independent Testing Laboratory and must reference the Batch Identification Number for each product tested.
- (f) A Processor shall keep records for each Batch of Hemp Extract 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. Lot Identification Number for raw materials used.
  - iii. Batch Identification Number assigned by the Processor.
  - iv. Extraction method used.
  - v. Quantity and type of all ingredients used to formulate the Hemp Extract.
  - vi. Amount of Hemp Extract manufactured.
  - vii. Certificates of Analysis demonstrating that all Hemp Extracts manufactured were tested by an Independent Testing Laboratory in accordance with Section III Testing Requirements, contain less than 0.3% total THC, all contaminant limitations have been met, and is in compliance with any other testing requirements or standards set by local state or federal law.
- (g) Hemp Extracts manufactured by a Processor with total THC in excess of 0.3% may not be used for the manufacture of Finished Products and may not be purchased, sold, or transferred for further Processing.

## **2. Manufacture of Finished Products**

- (a) Any Hemp or Hemp Extract used for manufacturing Finished Products shall only be obtained from a Producer or Processor Licensed by MDAR, 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.
- (b) Processors must ensure that any Hemp or Hemp Extract received for Processing complies with the testing requirements set forth by MDAR, including that it meets all THC limitations, contaminant limitations, and any other applicable testing requirements or standards set by local, state, or federal law and is accompanied by Certificates of Analysis that demonstrate compliance.
- (c) Processors must maintain records relative the raw material(s) used in the manufacture of Finished Products. The records shall be kept for a minimum of three (3) years and include, but not be limited to:
- i. Date of receipt or manufacture.
  - ii. Source information, including location of origin for the raw material(s).
  - iii. Batch or Lot Identification Number for the raw materials, name, License, and contact information for the Hemp Producer or Processor from whom the Hemp or Hemp Extract was obtained.

- iv. Certificates of Analysis demonstrating that the raw material(s) used for manufacturing Finished Products complies with the testing requirements set forth by MDAR, including that it meets all THC limitations, and complies with any other applicable testing requirements or standards set by local, state, or federal law.
- (d) Finished Products manufactured by a Processor must be assigned a unique Batch Identification Number. The Batch Identification Number should reference the Lot or Batch Identification Number for the raw materials used such that a Finished Product can be traced back to its origin.
- (e) For every Batch of Finished Product manufactured by a Processor, representative samples must be submitted to an Independent Testing Laboratory for testing potency and Cannabinoid Profile in accordance with the Protocol. Certificates of Analysis should be provided by the Independent Testing Laboratory and must reference the Batch Identification Number for each product tested.
- (f) Processors shall keep records for each Batch of Finished Product manufactured. Records shall be kept for a minimum for three (3) years. The records shall include, but not be limited to:
  - i. Date of manufacture.
  - ii. Quantity and type of all ingredients used to formulate the Finished Product, including Batch and/or Lot Identification Numbers for raw material(s) used.
  - iii. Batch Identification Number.
  - iv. Inventory of Finished Products.
  - v. Certificates of Analysis demonstrating that each Batch of Finished Product manufactured was tested by an Independent Testing Laboratory in accordance with Section III Testing Requirements, and contain less than 0.3% total THC.
- (g) Any Finished Product manufactured by a Licensed Processor must comply with any requirements put forth by the Federal Drug Administration and Massachusetts Department of Public Health.

#### **4. Labeling Requirements for Hemp Products**

- (a) Manufacturers shall ensure that all Finished Products are labeled in clear, legible wording no less than 1/16 inch in size on each container prior to transfer or sale.
- (b) Labels shall be firmly affixed and shall include the following:
  - i. Manufacturer name, License number and address.
  - ii. Cannabinoid profile and potency (must include THC and CBD concentrations).
  - iii. Batch Identification Number.
  - iv. State of origin for the Hemp or Hemp Extract used.
  - v. Statement: "This product derived from Hemp has not been tested, analyzed, or approved by the Massachusetts Department of Agricultural Resources or the FDA."
  - vi. Ingredients.
  - vii. Allergen warnings, as needed.
- (c) The Cannabinoid Profile should list amount per serving and total amount per container for each Cannabinoid present.
- (d) The label must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA, including in the name of the product itself.

### **III. TESTING REQUIREMENTS**

MDAR is utilizing the same testing requirements as the 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 by an Independent Testing Laboratory according to the [\*Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products\*](#) (“Protocol”). These testing protocols are available online at <https://masscannabiscontrol.com/wp-content/uploads/2021/06/Finished-Marijuana-Products-Sampling-and-Analysis-Protocol.pdf>.

The CCC may have additional requirements (such as testing, labeling, etc.) for hemp and hemp-derived products to be used or sold by a CCC Licensee. Hemp Producers, Processors, and CCC Licensees should ensure that any hemp material or finished hemp products to be purchased or sold by CCC Licensees are in compliance with all applicable requirements from both MDAR and the CCC.

### **IV. ENFORCEMENT**

MDAR 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 MDAR’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.

MDAR 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.