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EXECUTIVE OFFICE OF ENERGY AND ENVIRONMENTAL AFFAIRS



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## 2022 Hemp Processor Policy

**Effective Date:** October 17, 2022

**Program Application:** Commercial Processors of Hemp

**Approved By:** John Lebeaux, Commissioner

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

**Policy Number:** 2022-1 (Updates and replaces Policy 2021-1)

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 2021 Hemp Processor Policy.

### Purpose and Scope

This document sets forth MDAR’s updated Commercial Processor Policy (“Policy”). This Policy replaces the previous Interim Policy that was issued by MDAR on April 30, 2018 and updated on September 3, 2020 and October 4, 2021. 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.

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 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, MDAR will make every effort to 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.<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.

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

- 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. 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.
- It is important for any entity that would like to process Hemp 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.
  - 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.<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. Raw plant material includes but is not limited to the following:
  - Flower
  - Whole Plant
  - Leaves

## 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.

Commercial: Processing Hemp for market.

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

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.

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

Grower: A person that cultivates Hemp.

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.

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

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.

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.

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.

Licensee: The holder of a License from MDAR.

License: Authorization that is provided by MDAR 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 MDAR 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: delta-9 THC + (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
- Packaged and labeled hemp flower or plant material 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 products 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 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.

## **C. Hemp Products Not Allowed for Sale in Massachusetts**

Pursuant to 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 for sale 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 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;<sup>3</sup>
- Unprocessed or raw plant material, including the flower, that is meant for end use by a consumer except 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.

## **D. 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 MDAR, 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 MDAR a complete application, which includes the following information:

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<sup>3</sup> See,

[https://www.aafco.org/Portals/0/SiteContent/Announcements/Guidelines\\_on\\_Hemp\\_in\\_Animal\\_Food\\_May\\_1\\_2019.pdf](https://www.aafco.org/Portals/0/SiteContent/Announcements/Guidelines_on_Hemp_in_Animal_Food_May_1_2019.pdf).

- 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.

Applications are made available at the following website: <https://www.mass.gov/how-to/ma-industrial-hemp-program-licensing-during-the-open-application-period>. 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 31<sup>st</sup> of the year it was issued.

If an entity licensed through the CCC seeks to obtain hemp from a Licensed Hemp Processor or Producer and manufacture finished products using Hemp the CCC Licensee is not required to obtain a license through MDAR provided the finished products are not labeled or marketed as Hemp. If a CCC Licensee wants to manufacture finished products that are packaged and labeled as hemp or hemp-derived, the CCC Licensee must obtain a MA Hemp Processor License from MDAR. Licensed Hemp processing facilities may not be co-located with marijuana operations to ensure compliance with state and federal law.

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>4</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. 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 this Policy and the Hemp Production Regulations promulgated at [330 CMR 32.00](#).

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<sup>4</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.

Fee Schedule applicable to Processor Licenses<sup>5</sup>

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, 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.

4. 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 growing 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 proposed changes without prior written approval from MDAR.

5. 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.

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<sup>5</sup> 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.

## 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 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 31<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.

### **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](#).
- 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.

## **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, oil, or other Hemp Extracts from the plant.
- **Manufacturer:** Processor that creates a finished Hemp product that is packaged, labeled and ready for sale including but not limited to cloth, infused products and building materials.

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 Extract used for processing 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. 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 any Hemp or Hemp Extract received for processing complies with the testing requirements set forth by MDAR, including that it meets all THC limitations, and any other applicable testing requirements or standards set by local, state, or federal law.
- c. At the time of receipt, the Extractor shall assign the Hemp or Hemp Extract a lot number and maintain records relative to the receipt of the raw material used for Processing. 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 or Hemp Extract received
  - iii. Source information, including location of origin for the Hemp or Hemp Extract, and name, location, license and contact information for the Hemp Producer or Processor from whom the Hemp or Hemp Extract was obtained.
  - iv. Lot number assigned by Extractor for any Hemp or Hemp Extract used for Processing
  - v. Lab reports demonstrating that all Hemp or Hemp Extract obtained for Processing 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.
- d. 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 created
  - v. What raw material was used for Processing (grain, seed, fiber, oil, flower, etc.) and quantity used
  - vi. Lab testing results demonstrating that all Hemp Extracts produced contain less than 0.3% total THC, all contaminant limitations have been met, and any other testing requirements or standards set by local state or federal law.

2. Duties and Responsibilities of the Manufacturer

- a. Any Hemp or Hemp-derived product 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. 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. A Manufacturer 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, and any other applicable testing requirements or standards set by local, state, or federal law.
  - c. At the time of the receipt, the Manufacturer shall assign the Hemp or Hemp Extract a lot number and maintain records relative to the receipt of the raw material used for Processing. 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. Source information, including location of origin for the Hemp or Hemp Extract, name, location, license and contact information for the Hemp Producer or Processor from whom the Hemp or Hemp Extract was obtained.
    - iv. Lab testing results demonstrating that the Hemp or Hemp Extract used for Manufacturing finished products complies with the testing requirements set forth by MDAR, including that it meets all THC limitations, and any other applicable testing requirements or standards set by local, state, or federal law.
  - d. When the Manufacturer produces a finished product, records shall be kept for a minimum for three (3) years for each batch of the finished product. The records shall include, but not be limited to:
    - v. Date of production
    - vi. Batch number (must include lot number)
    - vii. Name and type of product
    - viii. Amount produced
    - ix. Lab reports demonstrating that the finished 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.
3. Labeling Requirements for the Manufacturer
- a. Manufacturers shall ensure that any products intended for human consumption (including but not limited to inhalation, ingestion, 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)
    - iii. Batch 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

### **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 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://masscannabiscontrol.com/wp-content/uploads/2021/06/Finished-Marijuana-Products-Sampling-and-Analysis-Protocol.pdf>. If test results exceed the limits set forth in the Testing Guidelines for heavy metal, biological, solvents (if used), or cannabinoids then MDAR must be notified. Failure to notify MDAR may result in the loss of your license. Testing for pesticide residue is not required at this time.

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.