# THE COMMONWEALTH OF MASSACHUSETTS

EXECUTIVE OFFICE OF ENERGY AND ENVIRONMENTAL AFFAIRS



# Department of Agricultural Resources

101 University Drive, Suite C-4, Amherst, MA 01002 413-548-1905 fax: 413-548-1901 www.mass.gov/agr



CHARLES D. BAKER Governor KARYN E. POLITO Lt. Governor MATTHEW A. BEATON Secretary

JOHN LEBEAUX Commissioner

## <u>Interim Policy</u> Commercial Industrial Hemp Program

Effective Date: April 30, 2018

**Program Application:** Commercial Growers and Processors of Industrial Hemp

Approved By: John Lebeaux, Commissioner

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

Policy Number: 2018-1

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, Hemp and Industrial Hemp, allowing Hemp to be grown commercially for Industrial Hemp or as part of an Agricultural Pilot Program.

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 and Industrial Hemp within the Commonwealth of Massachusetts.

#### **Purpose**

This document sets forth the Department's Commercial Industrial Hemp Program ("Program" or "Commercial Industrial Hemp Program") policy ("Policy") for the 2018 growing season. 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 growing and processing of Industrial Hemp and provides information on how to become a licensed Grower and Processor. During the interim Policy period the Department is focusing on licensing requirements under M.G.L. c. 128, Section 118. All proposed commercial activities related to the growing and processing of Industrial Hemp will need to obtain a license under this Policy in order to be considered in compliance with M.G.L. c. 128, Sections 116 through 123. The Department will address activities that may solely require registration at a later date and will not be issuing any registrations at this time. 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.

The Department will be promulgating regulations for future growing seasons after initiating stakeholder engagement and conducting the necessary public process to solicit input before final promulgation. This Policy will remain in place until such time as regulations are promulgated. While the Act and M.G.L. c. 128, Sections 116 through 123 authorize activities related to marijuana and Industrial Hemp in the Commonwealth, both are still considered illegal by the federal government as they remain Schedule I Controlled Substances under Title 21 of the Controlled Substances Act, 21 U.S.C. § 811. The only exception is for certain activities under Section 7606 of the 2014 Farm Bill (H.R. 2642), which allows for industrial hemp research conducted through state departments of agriculture and/or universities and institutions of higher education when the state has also authorized such activities. Section 7606 does not, however, allow for any activities related to marijuana or general commercial activities related to Industrial Hemp.

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#### **Key Risks and Considerations**

As noted above, while M.G.L. c. 128, Sections 116 through 123 authorize certain activities related to Industrial Hemp in the Commonwealth, such activities are still considered illegal by the federal government, with limited exceptions. As a result, the Department encourages all potential Program participants to consider the following risks and considerations.

#### Risks

- If you currently participate in or receive assistance from any activities or programs that are provided by the federal government or that utilize federal funds (i.e., loans, insurance, grants, management plans, etc.), you may no longer be entitled to continue or benefit from such activities or programs by virtue of engaging in activities permitted under this Policy.
- If the property on which you intend to grow your Crop is subject to an Agricultural Preservation Restriction ("APR") that was acquired with federal funds or that contains language prohibiting activities in violation of federal law, your ability to engage in activities permitted under this Policy may be limited or prohibited, and your eligibility for technical assistance or grants may be similarly restricted.
- If the total number of acres you intend to use to grow your Crop is less than two (2) acres, you will not be afforded any zoning enforcement protections afforded to commercial agricultural activities under M.G.L. c. 40A, Section 3.
- If your Crop tests higher than 0.3% THC, you will run the risk of being subject to an order of destruction of the Crop.

#### Other Considerations

- In order to ensure a Department-approved end use for your Crop, you will need to determine such end use prior to applying for a license and may wish to consider entering into an agreement with a Processor prior to cultivation. A Processor may also want to consider entering into an agreement with a Grower.
- Because Hemp is a relatively new Crop with limited or varied information about it, especially for cultivation in Massachusetts, you may wish to consider and think carefully about agricultural factors that may be unique to this Crop, including climate, size of acres grown, Crop loss, and soil conditions, such as high metal content.

<sup>&</sup>lt;sup>1</sup>Section 7606 of the 2014 Farm Bill recognizes the legitimacy of industrial hemp research conducted through state departments of agriculture and/or universities and institutions of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001) or a State department of agriculture. It does not, however, allow for the general commercial growing of hemp or industrial hemp in the United States and views both as Schedule I Controlled Substances under Title 21 of the Controlled Substances Act.

- You should consider how the application of plant nutrients may be affected by regulations promulgated at 330 CMR 31.00.
- You should consider existing restrictions on the use of pesticides that may impact the ability to grow the Crop.
- You may wish to consider whether indoor or outdoor growing, or a combination of both, would be best suited to the type and volume of Crop required for your business needs.

All questions related to the Commercial Industrial Hemp Program or this Policy can be directed to the Department at 617-626-1700.

## I. GENERAL INFORMATION

#### A. Definitions

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

- <u>Cannabidiol or CBD</u>: One of the several compounds produced by cannabis plants that have medical effects.
- <u>Cannabinoids</u>: Any of several compounds produced by cannabis plants that have medical and psychotropic effects. This includes but is not limited to CBD and THC.
- <u>Cannabinoid profile</u>: The amounts expressed as the dry weight percentages, of delta-nine-tetrahydrocannabinol, Cannabidiol, tetrahydrocannabinolic acid and cannabidiolic acid in a Hemp product.
- <u>Certificate</u>: 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.
- <u>Commercial:</u> Growing and/or Processing Industrial Hemp for sale. This excludes the growing of the Crop under the Agricultural Pilot Program.
- Crop: Hemp grown for the purposes of Industrial Hemp.
- Department: Massachusetts Department of Agricultural Resources.
- Extractor: A Processor that creates Industrial Hemp products from the Hemp plant. The Extractor will produce items such as fiber, seed, or oil from the plant.
- Grower: A person that cultivates Industrial Hemp.
- <u>Harvest Form: A form required</u> at least fourteen (14) days prior to harvest which includes location, variety and amount of Hemp produced, and an expected harvest or destruction date, whichever is applicable, and which allows the Department to coordinate with the Grower to schedule the required inspections and sampling required by M.G.L. c. 128, Section 122.
- <u>Hemp</u>: The plant of the genus cannabis and any part of the plant, whether growing or not, with a delta-9-tetrahydrocannabinol concentration that does not exceed 0.3 per cent on a dry weight basis or per volume or weight of marijuana product or the combined per cent of delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid in any part of the plant of the genus cannabis regardless of moisture content.

- <u>Industrial Hemp</u>: Hemp that is used exclusively for industrial purposes including, but not limited to, the fiber and seed. 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.
- Manufacturer: A Processor that creates an end product that is packaged, labeled and ready for sale from Industrial Hemp including but not limited to cloth, infused products, building products, and edibles
- Person: A natural person, corporation, association, partnership or other legal entity.
- <u>Planting Form:</u> A form, required no later than ten (10) days after planting, that indicates the location, variety, source, intended use, and expected harvest date of the Crop along with an inventory of any remaining Hemp seeds that were not planted after acquisition, and associated plans for storage or transfer to another licensed Program participant.
- <u>Processor</u>: A person that converts Industrial Hemp into a marketable form, including through extraction or manufacturing.
- THC: Delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid.
- <u>Volunteer Plant</u>: Any cannabis plant which grows of its own accord from seeds or roots in the years following an intentionally planted cannabis crop. Volunteer plants are not intentionally planted.

#### **B.** Approved Uses for Industrial Hemp

Pursuant to M.G.L. c. 128, Section 117(c), Industrial Hemp shall only be used for the following: (i) research purposes; and (ii) Commercial purposes considered reasonable by the commissioner. The Department considers the following uses for Industrial Hemp as reasonable:

- Fiber
- Seed
- Hemp seed oil
- Cannabidiol (CBD) that is derived from a Crop that is certified by the Department as Industrial Hemp
- Seed for cultivation
- Seed, seed meal, and seed oil for consumption
- Other reasonable Commercial purposes approved in advance by the Department as consistent with the purposes of M.G.L. c. 128, Sections 116 through 123.

If a Grower or Processor would like to use Industrial Hemp for a purpose not listed in this Policy, the Grower must submit a written request for that use to the Department prior to engaging in the proposed use. The Department will review the request and make a written determination as to whether the proposed use satisfies this Policy.

#### C. Application Requirements and Process for a Licensed Industrial Hemp Grower or Processor

At this time, any Person proposing to engage in the planting, growing, harvesting, possession, processing or selling of Industrial Hemp must obtain a license issued by the Department, depending on the type of activity.

#### <u>Licenses</u>

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

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 a Grower or Processor license. All licenses will expire on December 31<sup>st</sup> of the year it was issued.

Upon the approval of an application for a Grower or Processor license, the Department will notify the state police as well as local police in the municipality where the Crop will be grown. This notification will include the address and GPS coordinates of the Crop. The Department will also notify the chief administrative or executive officer<sup>2</sup> in the municipality where the Crop will be grown or processed in order to answer any questions or concern that they may have relative to the program. The licensee's address and security schematic or global positioning system coordinates that are provided to the chief administrator/executive offer and police 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.

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.

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<sup>&</sup>lt;sup>2</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.

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

#### 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 Industrial Hemp operation;
- Department issued license number;
- Signature of Department representative;
- A written finding that the Grower/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 material 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 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.

<sup>&</sup>lt;sup>3</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 Growers and 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 1<sup>st</sup> and November 15<sup>th</sup>. The Department will review all renewal applications in accordance, with M.G.L. c. 128, Sections 116 through123 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 Grower or Processors previous participation with the Program. The Department may deny a renewal under the Section 119(b) if it determines the Grower or Processor have not complied with this Policy or other statutes or regulations that govern the operation.

### II. GROWER INFORMATION

#### A. General Grower Information

#### 1. Seed Acquisition

Pursuant to M.G.L. c. 128, Section 117(b) (ii), a Grower shall only acquire Hemp seeds from a distributor that has been approved by the Department. The Department shall deem a distributor to be an "approved distributor" if it:

- Produces certified seeds that contain no more than 0.3% THC; and
- Provides documentation to the Grower showing THC levels are no more than 0.3% at the time the seed is received by the Grower.

An applicant for a Growers license will be required to certify that they agree to obtain seed with the necessary documentation and to provide this documentation to the Department prior to planting the Crop, or otherwise upon request.

The Department may require that a distributor provide additional information before the distributor is approved to distribute seeds in the Commonwealth

A Grower may not obtain seeds without first obtaining a license issued by the Department.

#### 2. Sign Posting

- a. A Grower must post a Department-approved sign at conspicuous points of entry to the area (greenhouse/field) where the Crop is grown. If there is more than one point of entry, a Grower must post a sign every 200 feet.
- b. Signs should be at least fourteen (14) inches by sixteen (16) inches with letters one (1) inch high and contain, at a minimum, the following:
  - i. Statement "Crop grown in this field is Industrial Hemp that is licensed by the Massachusetts Department of Agricultural Resources pursuant to M.G.L. c. 128, Sections 116-123.";
  - ii. Department issued license number;
  - iii. Emergency contact information (Name and phone number); and
  - iv. Department contact information: (617) 626-1700.

#### 3. Reporting of planting information to the Department

- a. Upon the Grower receiving the seed, the Grower must provide the Department with a copy of the seed certification obtained from the seed distributor demonstrating that the seed is at or below the 0.3% THC level.
- b. No later than ten (10) days after planting of the Crop, the Grower must submit the Department approved Planting Form to the Department.

### **B.** Inspection and Testing

The Department is authorized to conduct inspections and testing to ensure compliance of all activities authorized under M.G.L. c. 128, Sections 116 through 123. This includes compliance with the Policy as well as testing to ensure that THC levels of the Crop meet the limitations set by M.G.L. c. 128, Section 116.<sup>4</sup>

### 1. Inspections

- a. All Growers are subject to testing and inspections of Crops. The Department will make every effort to provide advanced notice of testing and inspections to the Grower unless such notice would impact the Department's ability to conduct necessary enforcement activities authorized by M.G.L. c. 128, Sections 116 through 123. Inspections will occur at the following stages:
  - i. License application process: Prior to issuing a license, the Department may schedule a site visit to the property. The purpose of this visit will be to review information that was provided during the application process and to also ensure a better understanding of the growing operation.
  - ii. Routine Sampling: The Department will test the Crop in order to ensure that the Crop does not exceed the 0.3% THC level, as required by the M.G.L. c. 128, Section 116. Sampling shall be conducted for all licensees prior to harvest and with the Grower present. Routine sampling will be scheduled in advance with the Grower or an authorized representative of the Grower
  - iii. Record Inspections: The Department may conduct routine record inspections to ensure that the Grower is maintaining all necessary information. This may include plant nutrient applications (330 CMR 31.00) and any other record keeping required by law.
  - iv. Follow up Inspection: The Department may conduct follow up inspections in order to determine if information provided by the Grower is true and accurate. This follow up may include planting and harvesting observations; sampling of the Crop; or additional record reviews. These inspections may be announced or unannounced.

#### 2. Testing

a. The Grower shall contact the Department no later than fourteen (14) days prior to harvest of the Crop or any portion of the Crop to schedule sampling for testing.

- i. The Department will collect samples of the Crop and bring material to a Department-approved lab for testing. The Grower or an authorized representative of the Grower must be present during the sampling.
- ii. The Grower shall harvest within ten (10) days of the collection of samples, unless otherwise authorized in writing by the Department. If harvesting after collection of samples but prior to receiving the sample results, the Grower must hold onto all harvested Crop material until a Certificate is issued from the Department.
- iii. The Grower shall submit the Department approved Harvest Form to the Department within ten (10) days of harvest.
- iv. If sample results show THC levels do not exceed 0.3% then a Certificate will be issued by the Department to the Grower. Upon receipt of a Certificate, the Grower may move the Crop off the licensed site if needed for processing or sale.

<sup>&</sup>lt;sup>4</sup> M.G.L. c. 128, Section 122 provides that "[t]he department may inspect and have access to the equipment, supplies, records, real property and other information deemed necessary to carry out the department's duties under sections 116 to 123, inclusive, from a person participating in the planting, growing, harvesting, possessing, processing, purchasing, selling or researching of hemp, industrial hemp. The department may establish an inspection and testing program to determine delta-9 tetrahydrocannabinol levels and ensure compliance with the limits on delta-9 tetrahydrocannabinol concentration."

v. If sample results show THC levels exceed 0.3%, then the Crop is no longer considered Hemp and the Grower is prohibited from harvesting the Crop for Commercial purposes or engaging in any other activities under this Policy. The Grower may also be subject to civil or criminal liability under state and federal marijuana laws. The Grower may opt for a second round of sampling at his/her own cost. If the second round of sampling of the Crop show THC levels higher than 0.3%, then the Grower may opt for a third round of sampling of the Crop while still in the ground or harvested Crop at his/her own cost. In the event that testing results show THC levels higher than 0.3%, the Grower will be instructed to destroy the Crop. The Grower and Department will enter into a written agreement setting forth the terms of such resolution and the Department will be present for the harvest and disposal of any Crop that does not comply with M.G.L. c. 128, Sections 116 through 123.

#### 3. Pesticide Use

The Department is charged with regulating pesticide use in the Commonwealth under M.G.L. c. 132B. The Department does not register any product that is not already registered by the United States Environmental Protection Agency ("EPA"). Currently, EPA does not allow the use of a registered pesticide on marijuana or hemp. There are products that are exempt from EPA registration as these products or the ingredients within them are considered minimum risk by EPA. Please refer to the following EPA website to find a list of products and active and inert ingredients that are exempt from registration: <a href="https://www.epa.gov/minimum-risk-pesticides">https://www.epa.gov/minimum-risk-pesticides</a>. The Department does not approve or provide for the registration of products for use on marijuana, including Hemp.

In the event a Grower uses a pesticide in violation of M.G.L. c. 132B or the regulations promulgated thereunder at 333 CMR 2.00 through 14.00, they may be subject to enforcement action by the Department.

#### 4. Energy Efficiency and Environmental Standards

Until such time that the Department issues its own policy on energy efficiency and environmental standards, any indoor facility used for Industrial Hemp cultivation, including greenhouses, must comply with guidelines issued by the Cannabis Control Commission, in consultation with the working group established under section 78(b) of the Act. If the Commission has not adopted guidelines by the time a Grower license is approved by the Department, the Grower is responsible for reviewing and understanding any guidelines that are adopted after that time. The Grower must ensure compliance with such guidelines, or other Department policies, issued by the time of the Grower's application for license renewal.

### C. Post-Harvest Activities

#### 1. Transport of Crop

Only a Grower or Processor licensed by the Department may transport Industrial Hemp and no Crop, or any portion thereof, may be transported without a copy of the Certificate issued by the Department. The Licensee must ensure that this Certificate stays with the Crop at all times and accompanies all shipments of the Crop, including any portion, so that anyone coming into contact with the Crop has access to written documentation demonstrating that the Crop was grown in compliance with M.G.L. c. 128, Section 116 and this Policy.

#### 2. End of the year reporting

The Grower shall submit an end-of-year report, on a form prescribed by the Department, with their renewal application or December 1<sup>st</sup> if not applying for renewal for the following year to the Department indicating, at a minimum, the following information:

- i. Variety Grown
- ii. Purpose of Crop

- iii. Harvested amount
- iv. End destination or use of Crop
- v. Volunteer Plants, if any occurred and how they were managed

#### 3. Volunteer Plants

It shall be the responsibility of the license holder to monitor and destroy Volunteer Plants that are discovered outside of the licensed growing area.

## III. PROCESSOR INFORMATION

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

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

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. A Processor may only take Industrial Hemp from a Massachusetts licensed Grower, unless otherwise authorized by federal law. The Department will require documentation demonstrating that such federal authorization is permitted.

- 1. Duties and Responsibilities of the Extractor:
  - a. An Extractor may only receive Crops from a Massachusetts licensed Grower.
  - b. The Crop must have the Department issued Certificate accompanying the Crop, which certifies that the Crop does not exceed 0.3% THC.
  - c. At the time of the 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. The records shall include, but not be limited to:
    - i. Date of receipt
    - ii. quantity received
    - iii. Grower information, including name, address of fields that were grown on, license information and contact information.
    - iv. Copy of the Certificate
    - v. Lot number assigned by Extractor
  - 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. Type of extraction method
    - iv. Amount extracted
    - v. What was extracted (grain, seed, fiber, oil, CBD)
    - vi. Lab testing results

2. Testing Requirements for the Extractor

a. If the Crop will be used for human consumption or absorption (including but not limited to, inhaling, eating, drinking, swallowing or topical application), the finished extraction must be tested at the times required by and for the following in accordance with Department of Public Health ("DPH") testing protocol ("Protocol")<sup>5</sup>, 6:

https://www.mass.gov/files/documents/2017/12/20/105cmr725.pdf

- i. Cannabinoid profile
- ii. Solvents
- iii. Pesticides
- iv. Metals
- b. All testing is the responsibility of the Extractor and must be done at a lab that has been registered by DPH to perform such testing<sup>7</sup>.
- c. All lab results must be sent to the Manufacturer with the finished extracted product.
- d. The Extractor shall send all lab reports to the Department within seven (7) business days of receipt of the results.
- e. If test results for the finished extraction exceed the limits set forth in the Protocol, then the finished extraction shall not be used in any product for human consumption or absorption. The Extractor therefore shall not sell the finished extraction to any Manufacturer or any other entity, or otherwise sell or use the extraction for human consumption or absorption. Instead, the Extractor may either destroy the product or work with the Department to find an alternate use for the finished extraction. Should an alternate use be found, the Extractor will enter into a written agreement with the Department setting forth the terms of any such resolution.
- 3. Duties and Responsibilities of the Manufacturer
  - a. The Manufacturer shall only receive extracted product (such as oil, seed, and fiber) from a Massachusetts licensed Extractor
  - b. 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 or Grower information including name, license number, and contact information.
    - iv. Lab results indicating cannabinoid profile, solvents, pesticides and metals
    - v. Extractor assigned batch and lot number
  - c. 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
- 4. 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, eating, drinking, swallowing or topical application), are labeled in clear, legible wording no less than 1/16 inch in size on each container.

<sup>6</sup> https://www.mass.gov/service-details/medical-use-of-marijuana-program-product-testing

- 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 is derived from Industrial Hemp."
  - v. Statement "This product has not been analyzed or approved by the FDA."
  - vi. Statement "This product derived from Industrial Hemp has not been tested or approved by the Massachusetts Department of Agricultural Resources."

## IV. Enforcement

The Department will make every effort to work with Growers and Processors to provide compliance assistance. However, it is the responsibility of the Grower or 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 revocation or denial of a license. In addition, failure to comply with the requirements may result in the issuance of fines. An entity has the right to appeal any enforcement action under M.G.L. c. 128, Section 123.

Pursuant to M.G.L. c. 128, Section 123, "[t]he department may establish civil administrative fines for violations of sections 116 to 123, inclusive. A person aggrieved by the assessment of a fine under this section or a licensure action under section 120 may appeal by filing a notice of appeal with the department not later than 21 days after the receipt of the notice of the fine or licensure action. The adjudicatory hearing shall be conducted in accordance with chapter 30A."

The Department will determine the amount of any fines imposed 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.