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EXECUTIVE OFFICE OF ENERGY AND ENVIRONMENTAL AFFAIRS



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POLICY STATEMENT REGARDING THE SALE OF HEMP-DERIVED PRODUCTS IN THE COMMONWEALTH
Updated October 4, 2021

This document sets forth the Massachusetts Department of Agricultural Resources ("MDAR") Policy Statement on the Sale of Hemp-Derived Products in the Commonwealth ("Policy"). This Policy provides notice of categories of hemp-derived products that are approved for sale in the Commonwealth and identifies products that are prohibited for sale. This Policy also provides information on how a person or entity may become licensed to sell as required by M.G.L. c. 128, Section 118. All proposed activities related to the sale of hemp-derived products must comply with this Policy in order to be considered in compliance with M.G.L. c. 128, Section 118.

Please note that this Policy applies only to hemp and hemp-derived products. All activities related to marijuana or the sale of any product containing marijuana are under the jurisdiction of the Cannabis Control Commission ("CCC") or law enforcement.

CONTROLLING LAW

The cultivation, processing, and sale of hemp in the Commonwealth of Massachusetts are regulated by both federal and state law.

With the passing of the Agricultural Improvement Act of 2018, referred to as the "2018 Farm Bill," signed on December 20, 2018, federal law now treats hemp as an agricultural commodity. Previously, hemp was not distinguished from marijuana under federal law, except under limited circumstances. Effective with this change in law, hemp is now legally recognized as a separate crop, the cultivation of which falls under the jurisdiction of the United States Department of Agriculture ("USDA") and state departments of agriculture, if approved by USDA. Additionally, the United States Food and Drug Administration ("FDA") retained its jurisdiction to address public health requirements for hemp-derived products under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and other related laws.

The FDA has also issued a statement that limits the types of cannabis-derived (including hemp-derived) products that may be manufactured and sold to consumers. In particular, the FDA has prohibited any food or other consumable products containing the cannabinoid known as "CBD" from interstate commerce without its approval.¹

Under state law, Sections 116 through 123 of Massachusetts General Laws Chapter 128 assign MDAR responsibility to regulate all activities related to hemp and industrial hemp within the Commonwealth of Massachusetts. The law directs MDAR to administer a licensing and registration program for the cultivation, processing, and sale of hemp and industrial hemp in the Commonwealth. More particularly, the law assigns MDAR general oversight responsibility for approving the sale of hemp-derived products for commercial purposes within the Commonwealth. MDAR's regulation of hemp-derived products is separate and in addition to controlling federal law, including FDA directives.

¹ See <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation>.

The Massachusetts Department of Public Health (“DPH”) is responsible for regulating food safety in the Commonwealth. DPH has recently issued policy guidance that is consistent with the FDA policy in prohibiting the manufacture or sale of any food or other consumable products containing CBD.² Under the state health and sanitary code, local boards of health have authority to enforce public health laws and regulations within a municipality.

SALE OF HEMP-DERIVED PRODUCTS

Under M.G.L. c. 128, Section 118, a license is required to “sell” industrial hemp (i.e. the products made from hemp). MDAR construes the term “sell” or “sale” of hemp to include the following sale transactions:

- Massachusetts Licensed Grower to Massachusetts Licensed Grower
- Massachusetts Licensed Grower to Massachusetts Licensed Processor
- Massachusetts Licensed Processor to Massachusetts retail facility (store)
- Massachusetts licensed Grower or Processor as authorized by M.G.L. c. 94G, Sections 4 and 12 to a Person licensed by the CCC and in accordance with any guidance or regulation promulgated by the CCC.

MDAR does not require Marijuana Establishments to be licensed to sell consumer-ready hemp or hemp-derived products purchased from MDAR licensees or products that use hemp or hemp-derived products as an ingredient.

Effective immediately, a person or entity that proposes to engage in the activities listed above shall be deemed licensed under M.G.L. c. 128, Section 118, provided that the person or entity is selling the hemp-derived products that are allowed under this Policy and is otherwise licensed as a Grower or Processor and in good standing with MDAR. Such products are also deemed approved commercial uses under M.G.L. c. 128, Section 117(c). No further action or approval by MDAR will be needed.

All persons or entities proposing to sell hemp-derived products in the Commonwealth are also responsible for complying with all applicable federal and state laws and regulations, including any regulations or guidance issued by the FDA, DPH, or local boards of health, except as otherwise authorized by law. Applicable laws and regulations are as follows:

- (a) Products for sale must be in compliance with the FDCA, as amended, and Section 351 of the Public Health Service Act, unless otherwise exempt in (d).
- (b) Products must be in compliance with applicable DPH guidance, unless otherwise exempt in (d).
- (c) Products must be allowed for sale under this Policy and, as such, be deemed to be approved commercial uses pursuant to M.G.L. c. 128, Section 117(c).
- (d) This Policy does not require that hemp-derived products sold to a Person licensed by the CCC for sale in a marijuana establishment comply with the FDCA, DPH, or local board of health requirements provided that such products are allowed by the CCC as authorized by the M.G.L. c. 94G, Section 12.

APPROVED HEMP-DERIVED PRODUCTS

The following hemp-derived products are approved for sale in the Commonwealth pursuant to M.G.L. c. 128, Section 117(c) and under FDA and DPH guidance:

- Hemp seed
- Hemp seed oil
- Hulled hemp
- Hemp seed powder
- Hemp protein

² See: <https://www.mass.gov/info-details/cbd-in-food-manufactured-or-sold-in-massachusetts>

- Clothing
- Building material
- Flower/plant from a Massachusetts licensed Grower to a 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.

HEMP AND HEMP-DERIVED PRODUCTS NOT APPROVED FOR SALE

The following products are **NOT** approved for sale in the Commonwealth pursuant to M.G.L. c. 128, Section 117(c) and are likewise prohibited for sale under FDA and DPH guidance:

- Any food product containing CBD;
- Any product containing CBD derived from hemp that makes therapeutic/medicinal claims;
- Any product that contains hemp as dietary supplement;
- Animal feed that contains any hemp products;³
- Unprocessed or raw plant material, including the flower, that is meant for end use by a consumer except to a Person licensed by the 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.

MDAR will provide compliance assistance to individuals licensed pursuant to M. G. L. c. 128 who are interested in engaging in the sale of any hemp or hemp-derived products. However, it is the responsibility of any person involved with the sale of hemp-derived products to review and understand M.G.L. c. 128, Sections 116 through 123 and this Policy.

Failure to comply may result in enforcement action from MDAR, DPH, the local board of health, or law enforcement. This may include the inability to sell any hemp-derived products in the future, the destruction or seizure of illegal products, loss of license, or further legal action to determine whether the product sold is in compliance.

LABELING OF FINISHED HEMP-DERIVED PRODUCTS

Manufacturers of finished hemp-derived products processed under M.G.L. Chapter 128 Section 118 must ensure that any products intended for human consumption or absorption (including but not limited to inhaling, swallowing or topical application), are labeled in clear, legible wording no less than 1/16 inch in size on each container.

Labels shall be firmly affixed and shall include the following:

1. Manufacturer name, license number and address
2. Cannabinoid profile (must include THC and CBD concentrations)
3. Batch number
4. State of origin for the Hemp or Hemp Extract used.
5. Statement: "This product derived from Hemp has not been tested, analyzed, or approved by the Massachusetts Department of Agricultural Resources or the FDA."
6. Ingredients
7. Allergen warnings, as needed

³ See: https://www.aafco.org/Portals/0/SiteContent/Announcements/Guidelines_on_Hemp_in_Animal_Food_May_1_2019.pdf

ADDITIONAL REQUIREMENTS FOR SALE OF UNPROCESSED OR RAW PLANT MATERIAL, INCLUDING FLOWER

Unprocessed or raw plant material, including the flower, that is meant for end use by a consumer remains prohibited in Massachusetts **except** as otherwise sold to a CCC Licensee for sale in a marijuana establishment in accordance with any guidance or regulation promulgated by the CCC as authorized by M.G.L. c. 94G, Sections 4 and 12. It is important to note that hemp produced in accordance with M.G.L. c. 128, Sections 116 through 123 and rules issued by the USDA is not subject to contaminant testing requirements from MDAR. Once a crop has been certified by MDAR to have Acceptable THC Levels, the hemp may be sold as-is unless the CCC or the CCC Licensee requires anything additional.

MDAR Licensees must keep records of the sale of any unprocessed or raw plant material, including flower, sold to a CCC Licensee. These records should include the MA Industrial Hemp Certificate(s) for any hemp sold and the amount sold (in lbs. weight.) These records must be made available to MDAR upon request.

Any unprocessed or raw plant material, including flower, sold to a CCC licensee must be accompanied by the following documentation provided by the Licensed Hemp Producer:

- MA Industrial Hemp Certificate(s)
- Amount sold (in lbs. weight)

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. For more information, please visit:

<https://masscannabiscontrol.com/wp-content/uploads/2021/05/Guidance-for-the-Retail-Sale-of-Hemp.pdf>