



STATE OF MAINE DEPARTMENT OF AGRICULTURE, CONSERVATION & FORESTRY DIVISION OF ANIMAL AND PLANT HEALTH 28 STATE HOUSE STATION

28 STATE HOUSE STATION Augusta, Maine 04333-0028

AMANDA E. BEAL COMMISSIONER

JANET T. MILLS GOVERNOR

January 8, 2020

Joint Standing Committee on Agriculture, Conservation and Forestry 100 State House Station Augusta, ME 04333-0100

RE: Review of Department of Agriculture, Conservation and Forestry Laws and Rules Regarding Hemp

Dear Honorable Senator Dill and Representative Hickman and Members of the Committee on Agriculture, Conservation and Forestry:

Pursuant to the Committee's request, the Department of Agriculture, Conservation and Forestry (Department) has completed a review of the laws and rules under its jurisdiction pertaining to hemp seeds and crops, agricultural commodities and products derived from hemp, and topical or ingestible consumer products, including food, food additives and food products derived from hemp.

Hemp Program:

The Department oversees the licensing of hemp grown both indoors and outdoors. Departmental Rules 01-001 CMR Chapter 247 established Rules for Growing Industrial Hemp in 2016. Due to the subsequent passage of PL 2019 c. 528 (7 MRS Chapter 406-A), the Department has incorporated the provisions of the new law into the Notice of Agency Rulemaking Proposal that was filed on December 18, 2020 *except* for the four areas outlined below. A copy of the proposed rules is attached. The Department held a hearing on the proposed Rules for Growing Hemp on January 7, 2020 and is accepting written comments on the rules until January 20, 2020.

Subjects not addressed by the current rulemaking proposal include:

• Licensing for possessors, processors, buyers or sellers as indicated in 7 MRS §2231(2) was not addressed. At present, the Department does not have the requisite expertise necessary to draft appropriately technical licensing standards for such activities. The Department will review and assess other state programs that do regulate such activities as a benchmark for potential future regulations and relevant funding support.

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- Licensing of hemp seed distributors is not covered (*see* 7 MRS §2231 (2-A)) in the proposed rules. Rather, the Department has required seed distributors to obtain a seed labeling license under the QAR rules CMR 01-001, Chapter 313 Seeds.
- We know of no current established scientific method to verify if plant materials used in breeding, tissue culture and cloning are hemp and not marijuana (*see* 7 MRS §2231(6)). However, the proposed rules do include a definition of a "Certified seed source" and we have required growers or breeders to provide a certificate of analysis from a third-party lab that shows the original parent plants tested at or below 0.3% THC.
- A specific reference to seeds saved by Maine growers in 7 MRS §2231(2-A) is not directly addressed in the current rules; however, it is covered by the definition of a "Certified seed source" in the proposed rules.

Regulating Hemp in Food:

The Department's of Quality Assurance and Regulation (QAR) Division works to ensure that food in commerce is free from adulteration or misbranding. Pursuant to 7 MRS Chapter 406-A, work has ensued regarding the regulation of cannabidiol (CBD) and other hemp isolates and hemp parts placed in products intended for human and/or animal consumption (note that the Department does not regulate topical products). For instance, a cooperative effort between the Department, the Attorney General's office, The Department of Health and Human Services, and the Office of Marijuana Policy resulted in the issuance of state guidelines pertaining to CBD that have been publicly distributed (see attached). In addition, QAR is finalizing new Standard Operating Procedures that clearly outline the requirements for packaging, labeling, and sales of packaged and unpackaged foods containing CBD, other hemp isolates, and hemp parts. Upon their finalization, the Department will provide the Committee with copies.

The Department is working hard to establish the regulatory framework necessary to support the growing hemp industry in Maine. We appreciate that the dynamic is fluid given ongoing Federal activities. We welcome input and continued dialogue with the Legislature in this area to try and be as responsive as possible to the needs of all stakeholders involved.

Very Truly Yours,

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Nancy McBrady, Director Bureau of Agriculture, Food and Rural Resources

cc: Amanda Beal, Commissioner

Encls.

01-001 DEPARTMENT OF AGRICULTURE, CONSERVATION AND FORESTRY

DIVISION OF ANIMAL AND PLANT HEALTH

Chapter 274: Rules for Growing Industrial Hemp

SUMMARY: These rules establish the requirements for becoming licensed to grow industrial hemp, including fees, application and licensing processes, and procedures for monitoring the growth of industrial hemp. The activities described in these rules may be considered a violation of federal law. Persons growing industrial hemp may be subject to federal sanctions for what may otherwise be considered authorized conduct in the State of Maine, and compliance with these rules does not exempt licensees from possible federal prosecution. The Department is not responsible or liable for the actions of industrial hemp growers under these rules.

I. Definitions

- A. <u>Certificate of analysis A report issued by a third-party ISO 17025 accredited</u> <u>laboratory, which indicates the delta-9-tetrahydrocannabinol,</u> <u>tetrahydrocannabinolic acid, and total tetrahydrocannabinol content of hemp on a</u> <u>dry weight basis.</u>
- B. <u>Certified seed source</u> A source of hemp seeds that are certified by a third party as producing hemp having a total delta-9-tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis. Certification may include a certificate of analysis from a third-party ISO 17025 accredited laboratory that indicates the parent plant seed source tested at or below 0.3% total delta-9-tetrahdrocannabinol on a dry weight basis.
- C. <u>Clone A hemp plant produced using any part of another hemp plant other than</u> the seeds of that hemp plant.
- D. <u>Commercial purposes</u> –Offering seed, plants, plant parts, extracts, or other derivatives of the hemp plant into commerce or distribution to another person for that purpose.
- E. Department The Maine Department of Agriculture, Conservation and Forestry.
- F. **Dry weight** The weight of hemp plant material with no greater than 12% moisture content.

G. <u>Growing area – The land or surface area on which a licensee cultivates or plans</u> to cultivate industrial hemp.

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- Hemp The plant Cannabis sativa L. and any part of that plant, including the seeds and all derivatives, extracts, cannabinoids, isomers, acids, salts and salts of isomers, whether growing or not, with a total THC [the sum of the concentration of delta-9 tetrahydrocannabinol and its precursor, (tetrahydrocannabinol acid multiplied by 0.8777)] concentration that is not more than 0.3% on a dry weight basis including any measurement of uncertainty, or as otherwise defined in federal law. "Hemp" includes agricultural commodities and products derived from hemp and topical or ingestible consumer products, including food, food additives, and food products derived from hemp, which in their final forms contain a total THC concentration of not more than 0.3% or as otherwise defined in federal law. "Hemp" does not include marijuana for medical use pursuant to Title 22, chapter 558-C, or adult-use marijuana pursuant to Title 28-B, chapter 1.
- I. <u>Indoor facility A building, greenhouse, cold frame, hoop house, high tunnel, or</u> other agricultural or horticultural method of enclosing the growing area.
- J. Law enforcement agency A federal, state, or local agency responsible for maintaining public order and enforcing the law, particularly activities involving prevention, detection, and investigation of crime, and the apprehension of violators.
- K. License The document issued to an individual after a successful application and review process, and following departmental receipt of a signed licensing agreement and submission of all licensing fees. The license allows the individual to possess, cultivate, grow and harvest industrial hemp under Maine law.
- L. Licensee An individual possessing an industrial hemp license.
- M. Licensing agreement A document signed by the licensee agreeing to abide by these rules and any other terms and conditions the Department deems necessary for enforcing the Industrial Hemp Law.
- N. Licensing period The time in which an industrial hemp license is valid. Licenses are issued for one year and expire on the 365th day after issuance. the calendar year in which the industrial hemp is to be grown, with an issue date of January 1 and expiration date of December 31, regardless of the actual date on which the license is issued.
- O. <u>Measurement of uncertainty The parameter, associated with the result of a</u> measurement, that characterizes the dispersion of the values that could reasonably

be attributed to the particular quantity subject to measurement.

- P. Non-contiguous growing area A growing area on which a licensee grows or plans to grow industrial hemp that is separated from other growing areas by more than 50 miles.
- Q. **Personal use** When a person cultivates three or less mature hemp plants on less than one acre of land area or an indoor facility, and no hemp plant parts, hemp products or hemp-infused products derived from that hemp are ever allowed to enter into commerce.
- R. <u>Sample Plant parts taken as representative of an individual plant or the</u> combined total plants in the growing area.
- S. <u>Strain A group of plants or an individual plant that exhibit(s) distinctive</u> observable physical characteristic(s) or has a distinct genetic composition.
- T. <u>Tetrahydrocannabinol (THC)</u> Delta-9-tetrahydrocannabinol, the natural or synthetic equivalents of the substances contained in the plant, or in the resinous extractives of, *Cannabis sativa* L., or any synthetic substances, compounds, salts, or derivatives of the plant or chemicals and their isomers with similar chemical structure and pharmacological activity.
- U. <u>Total tetrahydrocannabinol (THC) content</u> The maximum amount of possible delta-9 tetrahydrocannabinol in a hemp crop if total conversion were to occur which will be determined by the following calculation: [the sum of the concentration of delta-9 tetrahydrocannabinol and its precursor, (tetrahydrocannabinol acid, multiplied by 0.8777)] on a dry weight basis and reported to two significant figures:

 $\underline{Total THC} = ([\underline{delta-9 THC}] + ([\underline{THC-A}] * 0.877))$

- V. <u>Variety A group of plants or an individual plant that exhibit(s) distinctive</u> observable physical characteristic(s) or has a distinct genetic composition.
- A. Certified Seed Source A source of industrial hemp seeds that:
 - 1. Is certified according to Association of Official Seed Certifying Agencies (AOSCA) standards or other certification standards approved by the Department;
 - 2. The plants from which the seed was produced were tested during the active growing season and found to produce industrial hemp having a THC concentration that does not exceed 0.3% on a dry weight basis.
- B. Department The Maine Department of Agriculture, Conservation and Forestry.

C. Growing Area The land on which a licensee cultivates or plans to cultivate industrial hemp.

D. Industrial Hemp Any variety of *Cannabis sativa* L. with a delta-9tetrahydrocannabinol (THC) concentration that does not exceed 0.3% on a dry weight basis.

E. Industrial Hemp Law - An Act to Promote Industrial Hemp, Title 7 MRS Chapter 406-A § 2231.

F. Law Enforcement <u>Agency</u> — A federal, state or local <u>agency</u> responsible for maintaining public order and enforcing the law, particularly activities involving prevention, detection and investigation of crime and the apprehension of violators.

G. License The document that is issued to an individual after a successful application and review process and following departmental receipt of a signed licensing agreement and submission of all licensing fees. The license allows the individual to possess, cultivate, grow and harvest industrial hemp <u>under Maine law</u>.

H. Licensee An individual possessing an industrial hemp license.

I. Licensing Agreement – A document signed by the licensee agreeing to abide by these rules and any other terms and conditions the Department deems necessary for enforcing the Industrial Hemp Law.

J. Licensing Period The time in which an industrial hemp license is valid. Licenses are issued for the calendar year in which the industrial hemp is to be grown, with an issue date of January 1 and expiration date of December 31, regardless of the actual date on which the license is issued.

K. Non-Contiguous Growing Area A growing area on which a licensee grows or plans to grow industrial hemp that is separated from other growing areas by more than 50 miles.

L. **Sample** Plant parts taken as representative of an individual plant or the combined total plants in the growing area.

M. **THC** — Delta-9-tetrahydrocannabinol, the natural or synthetic equivalents of the substances contained in the plant, or in the resinous extractives of, *Cannabis sativa* L., or any synthetic substances, compounds, salts, or derivatives of the plant or chemicals and their isomers with similar chemical structure and pharmacological activity.

II. Application Process

A. Each applicant for a an industrial hemp license must submit a signed, complete, accurate, and legible application to the Department <u>at least 30 days prior to her/his</u> <u>intended planting date</u>. Applications will not be accepted after April 1 of the year in which the applicant wishes to grow industrial hemp. For 2016 only applications will be accepted until July 1.

B. Applicants applying to renew a license must submit the same information and fees as applicants applying for a new license. In addition, applicants for renewal must include, on the application, the licensing numbers of any previous licenses held and year of issuance of those licenses.

C. Only applications for industrial hemp grown outdoors will be considered. Indoor production of industrial hemp is not covered by these rules.

D. The applicant must provide:

- 1. Name, address and other contact information;
- 2. A detailed description of the land area <u>or indoor facility</u> to be used for the production of industrial hemp including, but not limited to: a map, aerial photograph or global positioning coordinates sufficient for locating production fields, <u>or the floor plan of any indoor facilities</u>, and showing the boundaries, dimensions, and size of the growing area;
- 3. A signed <u>and dated</u> statement that the applicant is the owner <u>or legal occupant</u> of the growing area <u>or indoor facility</u> to be used for cultivation of industrial hemp, or a statement, signed by the owner of the growing area <u>or indoor</u> <u>facility</u>, consenting to that use;
- 4. A copy of the certification showing the industrial hemp seed to be planted is from a certified seed source; and
- 5. The estimated planting date for the first crop.
- 4. <u>Any other information the Department determines is necessary for enforcing</u> the <u>Industrial Hemp Law and these rules.</u>

E. Each applicant for licensure shall submit a non-refundable application fee of \$100 with the application. Fees will not be refunded if a license is not granted.

F. Incomplete applications will not be processed.

G. False, inaccurate or misleading information provided on an application is grounds for license denial. Licenses may be denied to applicants who have previously had an a industrial hemp license revoked- or have violated any of rules or statutes contained in CMR 01-001 Chapter 274 or MRS Title 7, Chapter 406-A.

III. Issuance of Licensing Agreement and License

A. Upon approval of an application, the applicant for a license must pay the license fee. License fees are \$500 plus \$50100/acre of industrial hemp to be planted <u>outdoors and</u> \$500.00 plus \$0.25 per square foot of growing area for hemp to be planted indoors, as reported on the application. Indoor facilities that will plant hemp on multiple levels within a structure shall calculate the square feet of growing area by adding the surface area of each tier together. The maximum license fee for an individual license agreement shall be \$20,000. Partial acreage or square footage should be rounded up to the next whole acre or square foot. License fees must be paid prior to license issuance. <u>All license</u> fees are non-refundable for any reason.

B. Licenses are only for the site or sites listed on the license. Non-contiguous growing areas require a separate license.

C. Each applicant must sign a licensing agreement. The failure of the licensee to comply with any term or condition of the licensing agreement shall be grounds for license revocation. By signing the licensing agreement, the licensee agrees to the following terms and conditions:

- 1. Within 14 days after planting hemp seeds, seedlings or clones, the licensee shall provide a listing of the varieties of seeds, seedlings or clones planted and a copy of a certificate of analysis which indicates the parent plants for the planted seed, seedlings or clones were found to contain no more than 0.3% total THC on a dry weight basis.
- 2. Within 14 days of planting, the licensee shall provide a final legal description of the land area or indoor facility to be used for the production of hemp, and a map, aerial photograph or global positioning coordinates sufficient for locating each field, site or indoor facility where hemp is growing.
- 3. <u>The licensee will allow</u> the inspection and sampling of the industrial hemp crop at any and all times that the Department deems necessary.
- 4. All records relating to production, planting, cultivation, and harvest of the industrial-hemp crop must be kept for a period of 3 years. The records must be made available to the Department upon request.
- 5. The Department may require reporting of any information or data associated with the planting, cultivation, and harvest of the industrial hemp crop. The

Department may also require reporting of the types of commodities or products derived from the harvested hemp and manufactured or sold within or outside the state. The licensee must submit all required reports by the due dates specified by the Department.

- 6. <u>All-Information not deemed confidential by 7 MRSA § 2231, Section 9</u> provided to the Department and data collected by the Department through the industrial hemp licensing process may be publicly disclosed and may be provided to law enforcement agencies without notifying the licensee.
- 7. <u>Summary reports of information designated as confidential may be released to</u> the public using aggregate data that does not reveal the location of a field, site, or indoor facility where hemp is grown, handled or stored.
- 8. Licensees must comply with any other terms and conditions the Department determines necessary for enforcing the Industrial Hemp Law and these rules.

D. All licenses shall be valid for 1 year. The licensing period shall be January 1 to December 31.—Licensees must re-apply to participate in the program each year. All industrial <u>outdoor grown</u> hemp plant material must be planted and harvested within the licensing period. <u>Indoor grown hemp must be planted within the license period, and</u> <u>harvesting can take place in a concurrent license period after license renewal that occurs</u> within 30 days of the previous license expiration.

E. No industrial hemp plants shall be included in other licensed marijuana production programs. No growing area may contain *Cannabis <u>sativa</u>* L. plants, which the licensee knows or has reason to know are of a variety that will produce a plant that, when tested, will <u>contain</u> more than 0.3% <u>total</u> THC on a dry weight basis.

G. Amendments to an existing license are limited to reduction in the number of acres <u>or</u> <u>square footage</u> planted within the original growing area and changes to contact information.

- 1. Any licensee who wishes to reduce the growing area on which the licensee will conduct industrial hemp cultivation must submit to the Department, within 10 days of planting, an updated detailed description of the growing area including global positioning system location and map or a new floor plan for an indoor facility.
- 2. Additions to the original growing area <u>will not be accepted</u> <u>must be done</u> <u>through a new license application and new licensing agreement</u>.
- 3. Annual license fees are calculated based on the acreage reported in the application. No reimbursements of license fees shall result from a reduction in the actual number of acres or square footage of industrial hemp planted during any licensing year.

- 4. Any changes related to the information required under II. Application Process section D.1 must be reported to the Department within 10 days of the change.
- 5. Licenses are non-transferrable.

IV. Sampling and Inspection

A. All licensed industrial hemp growing areas are subject to sampling to verify that the <u>total</u> THC concentration of the industrial hemp planted does not exceed 0.3% on a dry weight basis.

B. The licensee will be notified prior to inspection and sampling. During inspection and sampling, the licensee or an authorized representative must allow complete and unrestricted access to all industrial hemp plants within the licensed growing area.

C. If an industrial hemp crop has not been inspected and sampled 15 <u>25</u> days prior to harvest, the licensee must notify the Department of intent to harvest the industrial hemp crop.

D. All industrial hemp plants within a growing area may be sampled to ensure compliance with the industrial hemp program.

- 1. Each sample will be divided into two parts. One part will be used for testing, and the other retained for retesting.
- 2. Quantitative laboratory determination of the <u>total</u> THC concentration on a dry weight basis will be performed.
- 3. A sample test result greater than 0.3% total THC shall be prima facie evidence that at least one <u>eCannabis sativa L</u>. plant or part of a plant in the licensed growing area contains THC above the allowable limit and the licensee is therefore not in compliance. Such a result shall be grounds to suspend or revoke the <u>industrial</u> hemp license, subject to an opportunity for the licensee to request a hearing. Any request for a hearing must be made to the Department, in writing, within 10 days of the receipt of the sample test result. Sample test results may be provided to the appropriate law enforcement agencies.
- 4. The licensee may request a retest of the retained portion of the sample. Any request for retesting must be made to the Department, in writing, within 10 days of the receipt of test results. The licensee must pay all analysis costs and shipping fees associated with the retest. If a retest is conducted, the results of the retest shall be final.

- 5. Crops testing above the allowable <u>total</u> THC limit <u>will must</u> be destroyed <u>by</u> <u>the grower according to instructions received from the Department.</u>
- 6. Upon completion of testing, any remaining samples will be destroyed 10 days after receipt of test results.

V. Violations

A. Any violation of 7 M.R.S. 406-A § 2231, or of these rules, may be enforced as a civil violation and shall be grounds for license suspension or revocation. Such violations include, but are not limited to:

- 1. Failure to comply with any term or condition of the license agreement;
- 2. Failure to provide any information required or requested by the Department for purposes of enforcing the Industrial Hemp Law or these rules;
- 3. Providing false, misleading or incorrect information pertaining to the licensee's cultivation of industrial hemp to the Department by any means, including but not limited to information provided in any application, report, record or inspection required or maintained for purposes of the Industrial Hemp Law or these rules;
- 4. Failure to submit a required report;
- 5. Failure to pay required fees;
- 6. Failure to destroy any crop following license revocation in accordance with Section V.B., below;
- 7. Growing <u>eCannabis sativa L.</u> that when tested is shown to have a <u>total</u> THC concentration greater than 0.3% on a dry weight basis; or,
- 8. Refusal or failure by a licensee or authorized representative to fully cooperate and assist with the inspection process.
- B. Licenses that are revoked for any reason will result in crop destruction.
 - 1. The licensee must destroy the crop in a manner approved by the Department within 10 days of notification of license revocation.
 - 2. The licensee is responsible for paying all costs associated with crop destruction.

STATUTORY AUTHORITY: 7 M.R.S. Chapter 406-A §2231

EFFECTIVE DATE:

AMENDED:



MAINE AGENCY GUIDELINES for ENFORCEMENT of PL 2019 c. 528[LD 1749]

Maine law, like the US Farm Bill of 2018, has expanded the definition of hemp to include cannabis plants and extracts of such plants (including cannabidiol or CBD) which have less than 0.3% delta-9-THC by dry weight. The US FDA retains the authority to regulate food, drug, and cosmetic products, including those containing hemp or cannabidiol/CBD. US FDA has issued statements prohibiting food, unapproved drugs, dietary supplements, pet food, and unapproved animal drugs that contain CBD from interstate commerce. In Maine, the Food Code had similar restrictions about CBD in food. Maine lawmakers responded with emergency enactment of PL 2019, c. 12 [LD 630], effective March 2019, and PL 2019, c. 528, effective September 19, 2019. These laws made changes to Maine's pure foods and drugs statutes and laws regarding hemp.

This guidance covers inspectors who enforce the Maine Food Code. This includes inspectors from the Department of Agriculture, Conservation and Forestry, which regulates retail food establishments, and the DHHS Health Inspection Program/designated municipalities, which regulate eating establishments. It is legal, per the Maine Food Code, for licensees to sell edible products containing CBD subject to the conditions outlined below:

- Per 22 MRS §2157(15) packaged food, food additives, or food products must be clearly labeled by including:
 - o the ingredient it contains (hemp or CBD) and amount by weight or volume;
 - o name and address of the source of the hemp from which the cannabidiol was derived;
 - o in the case of extracts (such as CBD oil) or tinctures, indicates the batch number; and
 - a disclosure statement that the food, food, additive or food product has not been tested or evaluated for safety; or
- Per 22 MRS §2157(15) unpackaged food, food additives or food products must:
 - clearly note the inclusion of CBD on a notice next to the food, food additive or product; next to the pertinent listing on a menu; or in an open manner where the food product is served, and
 - have a conspicuously displayed directory for use by customers with information on the contents of all unpackaged food products sold/served that contain CBD from hemp.
- The food product label, menu, advertising, and any other related information must not include health claims that items with hemp or CBD can diagnose, treat, cure or prevent any disease, condition or injury without approval pursuant to federal law.
- Source CBD may be from Maine or brought into Maine from another state that has a Farm Bill 2014 hemp program. The licensee must have the state hemp program number for the source CBD provider.
- The delta-9-THC content of any hemp, CBD extract, or product must be less than 0.3%.
- Ingestible products (food) may not be imported from out of state if they already contain CBD, since that is still a violation of federal law and the Maine Food Code. Ingestible products sold at retail in Maine must be produced in Maine.

These guidelines are for use by DHHS and DACF retail inspection staff. They will be enforced beginning December 1, 2019. These guidelines may be shared with the understanding that state and federal statutory changes and rulemaking are ongoing and may alter any of the above conditions and/or add new conditions.