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901:14-2-01

Definitions.

- (A) "Abandoned application" means an application for licensure which was returned to the applicant by the department as incomplete and not finalized or corrected by the applicant and returned to the department within thirty days.
- (B) "Acceptable hemp THC level" means the application of the measurement of uncertainty to the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis that produces a distribution or range that includes 0.3 per cent or less.
- (C) "Adulterated" has the same meaning as found in section 3715.59 of the Revised Code.
- (D) "Batch or lot" means the hemp products produced during a period indicated by a specific code.
- (E) "Controlled substance" has the same meaning as found in section 3719.01 of the Revised Code.
- (F) "Cosmetic" has the same meaning as found in paragraph (A)(5) of section 3715.01 of the Revised Code.
- (G) "Delta-9 tetrahydrocannabinol" of "THC" means the sum of the percentage by weight of tetrahydrocannabinolic acid multiplied by 0.877 plus the percentage by weight of delta-9 tetrahydrocannabinol.
- (H) "Department" means the Ohio department of agriculture.
- (I) "Dietary supplement" has the same meaning as found in section 3715.80 of the Revised Code.
- (J) "Director" means the director of Ohio department of agriculture or the director's designee.
- (K) "Disqualifying offense" means any felony involving a controlled substance including, but not limited to, violations of:
 - (1) Ohio Revised Code 2907.02(A)(1)(a).
 - (2) Ohio Revised Code 2907.05(A)(2).
 - (3) Ohio Revised Code 2923.16(D)(2).
 - (4) Ohio Revised Code 2923.241.
 - (5) Ohio Revised Code chapters 2925, 3719, and 3796.
- (L) "Drug" has the same meaning as found in paragraph (A)(3) of section 3715.01 of the Revised Code.
- (M) "Food" has the same meaning as found in paragraph (A)(2) of section 3715.01 of the Revised Code.
- (N) "Hemp" means 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 three-tenths per cent on a dry weight basis.
- (O) "Hemp product" means any product, containing a delta-9 tetrahydrocannabinol concentration of not more than three-tenths per cent, that is made with hemp. "Hemp product" includes hemp buds, flowers, cigarettes, cigars, shredded hemp, cosmetics, personal care products, dietary supplements or food intended for animal or human consumption, cloth, cordage, fiber, fuel, paint, paper, particleboard, and any other product

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containing one or more cannabinoids derived from hemp, including cannabidiol.

(P) "Immediate family" means a licensee's spouse, parents, children, grandparents, siblings, grandchildren, brother-in-law, sister-in-law, daughter-in-law, son-in-law, mother-in-law, father-in-law, step-parents, step-children, step-siblings, or a legal guardian or other person who stands in the place of a parent (in loco parentis).

(Q) "Key participant" means a sole proprietor, a partner in partnership, or a person with executive managerial control in a corporation. A person with executive managerial control includes persons such as a chief executive officer, chief operating officer and chief financial officer. This definition does not include non-executive managers such as farm, field, or shift managers.

(R) "Measurement of uncertainty" or "MU" means the parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.

(S) "Misbranded" has the same meaning as found in section 3715.60 of the Revised Code.

(T) "Process" or "processing" means converting hemp into a hemp product. Except that process or processing does not include on-farm drying, dehydrating, or packaging of raw hemp materials by a licensed hemp cultivator for sale directly to a licensed hemp processor.

(U) "Public park" means a park established by the federal government, state, or a political subdivision of the state including a county, township, municipal corporation, or park district.

(V) "Retail hemp production" means the production of hemp products that are prepared, served or otherwise held or handled for sale to the end consumer at the site of production. Retail hemp production includes a mobile retail facility.

(W) "School" means a child day-care center as defined under section 5104.01 of the Revised Code, a preschool as defined under section 2950.034 of the Revised Code, or a public or nonpublic primary school or secondary school.

(X) "University" means an institution of higher education as defined in section 3345.12 of the Revised Code and a private nonprofit institution with a certificate of authorization issued pursuant to Chapter 1713. of the Revised Code.

(Y) "USDA" means the United States department of agriculture.

(Z) "Wholesale hemp production" means the production of hemp products that are processed, packaged, manufactured, or otherwise held or handled for distribution to another location or for sale at wholesale.

901:14-2-02 Processing License.

(A) No person shall process hemp without a hemp processing license issued by the department.

(B) Hemp processing licenses are valid for a period of three years provided that the licensee is compliant with Chapter 928 of the Revised Code and the rules of this Chapter.

(C) Hemp processing licenses shall be renewed every three years by complying with the rules of this paragraph, including obtaining the required background check(s) as outlined in rule 901:14-2-05.

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(D) The department may only issue a hemp processing license if the applicant has:

- (1) Submitted a complete application as outlined in rule 901:14-2-03;
- (2) Submitted both the application fee, if during the first year of licensure, and the annual license fee as outlined in rule 901:14-2-04;
- (3) Completed the required background check(s) as outlined in rule 901:14-2-05 of the Administrative Code and the applicant and no key participant of the business entity has, within the last ten years, plead guilty to or been convicted of a disqualify offense.
- (4) Successfully passed the initial facility inspection performed by the department to determine that the facility is in compliance with Chapter 928 of the Revised Code and the rules of this Chapter.

(E) Prior to years two and three of the license period, licensees shall remit the annual license fee to the department.

(F) Any licensee or key participant in the business entity who, during the time of licensure, pleads guilty to or is convicted of a disqualifying offense shall have their license revoked or suspended by the department if the licensee or key participant is not removed from the entity within thirty days from the date of plea or conviction.

(G) A processing license is valid only for the individual or business entity, and the key participants in the business entity, for which it is issued. A processing license may only be transferred or assigned if:

- (1) The licensee notifies the department in writing of the proposed transfer or key participant change;
- (2) The licensee ensures that the background checks as outlined in rule 901:14-2-05 have been completed; and
- (3) The licensee can demonstrate that the licensee will remain in compliance with the rules of this Chapter.

(H) A processing license is valid only for the facility which was inspected at the time of original licensure.

(I) The following are not required to obtain a processing license under this Chapter:

- (1) A university who has been specifically authorized by the director to process hemp for research purposes.
- (2) Any person who is a subordinate employee or immediate family member of the licensed processor so long as these individuals are acting under the instructions and control of the licensed processor within the licensed facility. Any actions taken by these individuals shall be the responsibility of the licensed processor.

901:14-2-03 Processing application.

(A) A person applying for a hemp processing license shall apply on a form provided by the department.

(B) An applicant shall provide all of the following information to the department:

- (1) If the applicant is an individual:

- (a) The full legal name of the applicant;

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- (b) The physical address of the applicant;
- (c) The mailing address of the applicant;
- (d) The email address of the applicant; and
- (e) The phone number of the applicant.

(2) If the applicant is a business entity:

- (a) The full name of the business;
- (b) The federal tax identification number of the business;
- (c) The mailing address of the business;
- (d) The principal business location in the state of Ohio;
- (e) The full name of the individual who is authorized to sign on behalf of the business entity;
- (f) The full name, title, and email address of the individual(s) who will be primarily responsible for the hemp operations of the business entity;
- (g) The identity of every key participant in the business entity applying for licensure;
- (h) The information required in paragraph (B)(1) of this rule for each party identified in paragraph (B)(2)(g) of this rule;
- (i) Phone number for the business entity; and
- (j) Email address for the business entity.

(3) For each processing location:

- (a) The global position system coordinates;
- (b) The physical address; and
- (c) Maps for each building or storage facility where hemp will be processed or stored.

(4) List of the types of hemp products that will be produced.

(5) Any other information required by the department.

(C) If applicable, the applicant shall provide the following:

- (1) The extraction operational plan as outlined in rule 901:14-2-11.
- (2) Documentation that the applicant is currently in compliance, with all building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the applicant's property is located, which are in effect at the time of the application, including but not limited to building department approval demonstrating compliance with rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code and any applicable zoning considerations.

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- (D) Any incomplete application will be returned to the applicant by the department.
- (E) Abandoned applications shall not be reviewed by the department and destroyed.
- (F) Failure to remit required fees in a timely or complete manner may result in the department taking enforcement action as defined in rule 901:14-2-99.

901:14-2-04 Fees.

- (A) Processing Fee Schedule.
 - (1) The application fee shall be \$100 for each processing application.
 - (2) The annual license fee shall be \$500 for processing the raw grain component of hemp for each processing site.
 - (3) The annual license fee shall be \$500 for processing the raw fiber component of hemp for each processing site.
 - (4) The annual license fee shall be \$3000 for processing the raw floral component of hemp for each processing site.
 - (5) The annual license fee for processors using cannabinoids in human and animal food, dietary supplements, cosmetics, and personal care product for each processing site shall be:
 - (a) \$500 for wholesale production; and
 - (b) \$250 for retail production.
 - (6) A processor of more than one component shall pay the annual license fee of each component.
 - (7) All samples taken pursuant to the chapter shall be taken free of charge for testing conducted by the department. The samples become the property of the department and are non-returnable.
- (B) The fees established in this section shall be nonrefundable.

901:14-2-05 Background checks.

- (A) All applicants and key participants in the business entity, if applicable, shall submit to a criminal records check completed by the bureau of criminal identification and investigation in accordance with section 928.03 of the Revised Code.
- (B) Applicants submitting a renewal application must comply with paragraph (A) of this rule prior to the expiration of their existing license.
- (C) The department shall not grant a license to an applicant unless the applicant and all key participants complete a criminal background check and have not plead guilty or been convicted of a disqualifying offense in the ten years prior to applying for a license. No background check that was completed in excess of sixty-days prior to application can be accepted by the Department.

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(D) The applicant requesting a criminal records check shall submit with a request to the bureau of criminal identification and investigation: a completed copy of a form prescribed under division (C)(1) of section 109.572 of the Revised Code; a set of fingerprint impressions obtained as described in division (C)(2) of section 109.572 of the Revised Code; the applicant's name and address; the department's name and address; and, a request that the superintendent of the bureau of criminal identification and investigation obtain from the federal bureau of investigation any information it has pertaining to the applicant.

(E) The department shall only accept results of a criminal records check submitted to the department directly from the bureau of criminal identification and investigation.

(F) The applicant shall bear all costs associated with the criminal records check as determined by the bureau of criminal identification and investigation, the federal bureau of investigation, and by any agency with authority to charge a fee for fingerprint impressions.

(G) If the department does not receive the background check of all required parties within thirty days of submitting their application, the application shall be deemed an abandoned application unless the applicant requests an extension waiver of thirty days to complete the background check requirement. If the department does not receive the background check by the end of the extension period, the department will consider the application abandoned.

901:14-2-06 Land use restrictions for licensed processors.

A licensed processor shall not:

(A) Process or store any cannabis that is not hemp.

(B) Process or store hemp or hemp products on any site not approved by the department.

(C) Process, handle, or store hemp or hemp products in a building used as a personal residence or on land that is zoned for residential use.

(D) Process, handle or store hemp or hemp products in or adjacent to any structure that is used or zoned for residential purposes.

(E) Process hemp in any location, unless prior approval is received in writing from the department, that is located within five hundred feet of the boundaries of a parcel of real estate, measured from the closest point of the property lines, having situated on it a school or public park. Except that this does not apply to research being conducted by a university that is approved by the director

901:14-2-07 Financial responsibility.

(A) Any licensed processor who purchases raw, unprocessed hemp plant material shall meet the standards of financial responsibility required under this rule.

(B) Each licensed processor having sold equal to or less than \$100,000 of raw, unprocessed hemp plant material in the previous calendar year shall have and maintain a surety bond in the amount of \$10,000. Each licensed processor having sold more than \$100,000 of raw, unprocessed hemp plant material in the previous calendar year shall have and maintain a surety bond in the amount of \$20,000.

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(C) In order to demonstrate the financial responsibility required in paragraph (B) of this rule, the licensed processor shall file a surety bond issued by a corporate surety company that is authorized to do business under the laws of this state with the department. The surety bond shall be subject to redemption by the state only upon a suspension, revocation, or insolvency of a licensed processor for the purpose of repaying the licensed processor's obligations to creditors which are licensed cultivators pursuant to division 901:14-1 of the Ohio Administrative Code. Redemption shall only be for an amount equal to the claims made by creditors which are licensed cultivators. Regardless of the amount of claims made against the bond and the number of periods the bond covers, the maximum liability under the bond is the penal sum. The bond shall be continuous. The bond shall, however, include a provision for cancellation, subject to a notice period of 30 days with notice provided to the processor and to the department.

901:14-2-08 Inspection and sampling.

(A) All hemp processing facilities shall be subject to inspection and sampling by the department for compliance with chapter 928 of the Revised Code and the rules of this chapter.

(B) Representatives of the department shall be provided with complete and unrestricted access to all hemp and other cannabis plants, and all land, buildings, and other structures used for the processing, handling, and storage of all hemp and other cannabis plants; and all locations listed in the license application.

(C) Samples may be collected by the department and tested to determine compliance with chapter 928 of the Revised Code and the rules of this chapter.

(D) All samples taken pursuant to the rule shall be provided for testing conducted by the department at no cost to the department. The samples become the property of the department and are non-returnable.

901:14-2-09 Food safety regulations.

All hemp processors shall comply with all applicable federal food safety regulations adopted in Chapter 901:3-17 of the Ohio Administrative Code.

901:14-2-10 Sources.

(A) All hemp processors extracting cannabinoids from hemp plant material shall obtain these materials from:

(1) A licensed hemp cultivator in the state of Ohio;

(2) A licensed cultivator in another state or jurisdiction's hemp program which has been approved by the United States Department of Agriculture under 7 U.S.C. 1639; or

(3) An entity residing in a foreign jurisdiction where the hemp material has been tested in accordance with rule 901:14-1-10 of the Administrative Code.

(B) All hemp processors using extracted cannabinoids in their hemp products shall obtain the extracted material from:

(1) A licensed hemp processor in the state of Ohio; or

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(2) An entity residing in a jurisdiction where the extracted cannabinoids have been extracted and tested in accordance with rule 901:14-2-12 through rule 901:14-2-15 of the Administrative Code.

(C) During the extraction process, all extracted cannabinoids must be brought down to a delta-9-tetrahydrocannabinol within the acceptable hemp THC level before final formulation or manufacturing of the final product. At no point shall an extracted oil which exceeds the acceptable hemp THC level be added to another hemp product.

(D) Hemp processors shall maintain records indicating compliance with paragraphs (A), (B), and (C) of this rule in accordance with rule 901:14-2-18 of the Administrative Code.

901:14-2-11 Extraction operational plan.

All processors extracting cannabinoids from hemp plant material shall have and follow an operational plan. The plan shall include at a minimum:

(A) Implementation of standards and guidelines for processing of plant material and the extraction of cannabinoids;

(B) Establish training and safety policies for the safe operation and maintenance of any and all equipment that will be used for extracting cannabinoids to ensure that any person involved in processing hemp:

(1) Has been fully trained in the safe operation and maintenance of any and all equipment that will be used for hemp extraction, with supporting documentation of the training;

(2) Has been fully trained in the safe use, handling, and storage of any and all chemicals that will be used for hemp extraction, in accordance with OSHA protocols, with supporting documentation of the training;

(3) Has been fully trained in the safe and sanitary execution of any applicable post-extraction refining protocols; and

(4) Has been fully trained in the safe and sanitary execution of any applicable manufacturing processes, including any applicable food safety standards under Chapter 901:3-117 of the Administrative Code.

(C) Documents the processing and extraction methods, techniques, and standards used which complies with rule 901:14-2-12 of the Administrative Code.

901:14-2-12 Extraction methods and training.

A processor may only use the methods, solvents, and gases set forth in this rule in the manufacture of hemp products.

(A) A processor may use hydrocarbon solvent-based extraction methods in a spark-free and properly ventilated environment, isolated from any open flame or ignition source, and may use the following solvents, at a minimum of ninety-nine per cent purity, in a professional grade, closed-loop extraction system designed to recover the solvents:

(1) Propane;

(2) N-butane;

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(3) Isobutane;

(4) Heptane; or

(5) Other solvents exhibiting minimal potential toxicity to humans with the approval of the department.

(B) A processor may use carbon dioxide-based extraction methods using food grade carbon dioxide at a minimum of ninety-nine per cent purity in a professional grade, closed-loop system in which each vessel is rated to a minimum pressure to accommodate the specific extraction protocol, including supercritical, liquid, and subcritical.

(C) A processor may use ethanol at a minimum of ninety-nine per cent purity to produce extracts for use in the manufacture of hemp products.

(D) A processor may use food grade glycerin and propylene glycol in the manufacture of hemp products.

(E) A processor may use non-solvent extraction methods involving the mechanical separation of cannabinoids from plant material to produce hemp extracts for use in the manufacture of hemp products.

(F) A processor shall comply with all applicable OSHA regulations as well as comply with and pass inspection for any applicable fire, safety, and building codes pertaining to the use and storage of the equipment and solvents used in the manufacture of hemp products.

(G) A processor using hydrocarbon solvent-based or carbon dioxide extraction methods shall designate at least one individual to train and supervise employees in the use of extraction equipment and associated solvents who has earned, at minimum, a bachelor's degree in engineering or physical sciences from an accredited university, or who has at least three years of experience in the operation of the equipment being used in the facility or similar equipment.

901:14-2-13 Laboratory testing.

(A) All hemp products prior to being offered for sale shall be tested in accordance with this rule.

(B) The hemp processor shall select a random sample from every batch or lot of hemp products produced at their facility that is of sufficient quantity to perform the required tests. The sample shall be tested by a testing laboratory which meets the requirements of rule 901:14-2-14 of the Administrative Code.

(C) Unless otherwise stated in paragraph (G) of this rule, a processor shall have the testing laboratory test every required hemp product sample for:

(1) Microbial contaminants of public health concern;

(2) Cannabinoid potency including, at minimum:

(a) Delta-9-tetrahydrocannabinolic acid (THCA);

(b) Delta-9-tetrahydrocannabinol (THC);

(c) Cannabidiolic acid (CBDA);

(d) Cannabidiol (CBD); and

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(e) All other cannabinoids listed on the product label.

(3) Mycotoxins:

(4) Heavy metals, including, at a minimum, arsenic, cadmium, lead, and mercury; and

(5) Residual solvents, if a solvent other than carbon dioxide was used in the extraction process, if applicable.

(D) The processor shall have the testing laboratory estimate and report the measurement of uncertainty with the test results for the cannabinoids listed in paragraph (C)(2) of this rule.

(E) The processor shall obtain from the testing laboratory a certificate of analysis that meets the requirements of rule 901:14-2-15 of every hemp product sample tested.

(F) A processor shall not sell or otherwise distribute the hemp product unless the product meets the standards set forth in Chapter 928 of the Revised Code and the rules of this Chapter.

(G) Exceptions:

(1) Hemp products which are used exclusively for fiber purposes are exempt from compliance from rules 901:14-2-13 through 901:14-2-15 of the Ohio Administrative Code.

(2) Hemp products derived exclusively from hemp seed are exempt from compliance from rules 901:14-2-13 through 901:14-2-15 of the Ohio Administrative Code.

(3) Hemp products that contain a hemp extract or cannabinoids are exempt from the testing requirements found in paragraphs (C)(1) and (C)(3) through (C)(5) so long as:

(a) The hemp extract and/or cannabinoids were acquired from a source identified in rule 901:14-2-10; and

(b) The hemp extract and/or cannabinoids were accompanied with a certificate of analysis that meets the requirements of rule 901:14-2-15; and

(i) The certificate of analysis matches the batch or lot used in the production of the hemp products by the processor; and

(ii) The certificate of analysis was produced by a laboratory which meets the requirements of rule 901:14-2-14.

901:14-2-14 Testing laboratories.

For the purposes of this Chapter, "testing laboratory" means any laboratory which is accredited to the 2017 edition of ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" standard by a non-profit accreditation body that is signatory to the "International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA)" and which operates in accordance with ISO/IEC 17011 "General Requirements for accreditation Bodies Accrediting Conformity Assessment Bodies."

The methods utilized by the laboratory in testing done pursuant to this Chapter must be within their scope of accreditation.

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901:14-2-15 Laboratory reporting.

(A) A licensed processor shall ensure that the testing laboratory selected create a unique certificate of analysis for each batch or lot tested on its behalf, which shall include, at minimum:

- (1) The name and address of the testing laboratory where the analysis was performed;
- (2) The ISO certification number of the testing laboratory;
- (3) The name of the processor from whom the sample was received;
- (4) The address of the processing facility where the sample was processed;
- (5) The name of the product tested;
- (6) A unique batch or lot number that will match the hemp product, in order to facilitate any warnings or recalls the department deems appropriate;
- (7) The date or dates on which each test was performed;
- (8) The date or dates the sample was collected;
- (9) The cannabinoid profile of the sample, including the percentage content by weight for, at minimum:
 - (a) Delta-9-tetrahydrocannabinol (THC);
 - (b) Delta-9-tetrahydrocannabinolic acid (THCA);
 - (c) Cannabidiol (CBD);
 - (d) Cannabidiolic acid (CBDA); and
 - (e) All other cannabinoids listed on the product label.
- (10) Results of analysis for microbial contamination, as applicable;
- (11) Quantitative results of analysis for heavy metal contamination, as applicable;
- (12) Quantitative results of analysis for mycotoxins, as applicable;
- (13) Quantitative results of analysis for residual solvents, as applicable; and
- (14) The signature of the laboratory manager or scientific director certifying the analysis.

(B) The certificate of analysis may contain the following:

- (1) Results of quantitative analysis of additional cannabinoids for which the laboratory is able to obtain a standard for comparison; and
- (2) Results of quantitative analysis of terpenes for which the laboratory is able to obtain a standard for comparison.

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901:14-2-16 Processor waste disposal.

(A) For the purpose of this rule, "hemp byproducts and waste" means a byproduct, produced as a result of processing hemp, that contains more than 0.3 per cent THC by dry weight basis.

(B) A licensed processor shall dispose of hemp byproducts or waste in such a manner as to render the hemp byproduct or waste unusable.

(C) Hemp byproducts or waste that is rendered unusable shall be discarded into a locked dumpster or other approved, locked container for removal from the facility by a waste removal company selected by the processor. Hemp byproducts or waste shall be rendered unusable by the processor by grinding and incorporating the hemp byproducts or waste with one or more of the non-consumable, solid wastes listed below, such that the resulting mixture is at least fifty-one per cent non-hemp byproduct or waste:

- (1) Paper waste;
- (2) Cardboard waste;
- (3) Food waste;
- (4) Yard waste;
- (5) Soil or other growth media;
- (6) Other wastes approved by the department.

(D) The processor shall maintain and make available in accordance with this chapter a separate record of every disposal indicating:

- (1) The date and time of disposal;
- (2) The manner of disposal;
- (3) The volume and weight of approved solid waste used to render the hemp byproducts or waste unusable;
- (4) The reasoning for and description of the disposal;
- (5) The batch number or numbers, volume, and weight of any hemp extract or plant material being disposed of; and
- (6) The lot number, product name, volume, weight, and unit count of any hemp product being disposed of.

901:14-2-17 Labeling.

(A) All hemp products, except for those made exclusively from hemp fibers, shall be labeled:

- (1) In accordance with the following standards:
 - (a) The labeling requirements found in rule 901:3-1-11 of the Administrative Code.
 - (b) The standard of identity requirements found in rule 901:3-1-12 of the Administrative Code.

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(c) The food coloring requirements found in rule 901:3-1-13 of the Administrative Code.

(2) With the milligrams per serving for all cannabinoids as identified on the product label, if the hemp product meets the definitions of either a food or dietary supplement as found in rule 901:14-2-01 of the Administrative Code.

(3) With the total milligrams per unit for all cannabinoids as identified on the product label, if the hemp product meets the definitions of a cosmetic product as found in rule 901:14-2-01 of the Administrative Code.

(4) With the cannabinoid profile of the product that matches the laboratory reporting for each unique batch or lot as required in paragraph (A)(9) of rule 901:14-2-15 of the Administrative Code, if the hemp product does not meet the definitions of food, dietary supplement, or cosmetic products as found in rule 901:14-2-01 of the Administrative Code.

(5) With the unique batch or lot coding that will match the hemp product with a batch or lot, in order to facilitate any warnings or recalls the department deems appropriate.

(a) Each container or product shall be marked with an identifying code permanently visible to the naked eye.

(b) The required identification shall specify in code the establishment where the product was packed, the product contained therein, and the year, day, and period during which it was packed.

(c) The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution.

(d) Codes may be changed periodically on one of the following bases:

(i) Intervals of four to five hours;

(ii) Personnel shift changes; or

(iii) Batches, as long as the containers constituting the batch do not represent those processed during more than one personnel shift.

(6) With a statement, if the products contain cannabinoids, indicating that consumers should consult a licensed healthcare professional if pregnant, breast feeding, currently taking medications, or under 18 years of age.

This statement shall appear prominently and conspicuously as compared to other words, statements, or designs on the information panel of the immediate container label, but in no case may the letters be less than 1/16 inch in height. Where the immediate container is not the retail package, this warning statement shall also appear prominently and conspicuously on the information panel of the retail package label.

This requirement does not apply to products derived exclusively from hemp seed oil.

(B) Hemp product labeling requirements by classification:

(1) All hemp products which meet the definition of a food as found in 901:14-2-01 shall meet the labeling requirements in 21 C.F.R. 101.9 (2018).

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- (2) All hemp products which meet the definition of a dietary supplement as found in 901:14-2-01 shall meet the labeling requirements in 21 C.F.R. 101.36 (2018).
- (3) All cosmetic products shall be labeled in accordance with 21 C.F.R. Part 701 (1974) and 21 C.F.R. 714 (2019) as applicable.

901:14-2-18 Records.

(A) Each processor shall keep and maintain upon the licensed premises for a five-year period, unless otherwise stated in these rules, true, complete, legible, and current books and records. All required records must be made available for inspection if requested by the department. The following records shall be maintained:

- (1) Records relating the purchase of raw, unprocessed plant material including:
 - (a) Name and license number of licensed cultivator from which the processor purchased the material;
 - (b) If the licensed cultivator is licensed in a state or jurisdiction other than Ohio, the state or jurisdiction of licensure, their address, and a copy of their cultivator license;
 - (c) A bill of sale or other document that indicates the purchase price, purchased quantity, and date of sale;
 - (d) The certificate of analysis from the appropriate laboratory authority which indicates that the purchased material meets the definition of hemp; and
 - (e) A document indicating the total purchase amount of raw, unprocessed plant material in the last calendar year.
- (2) Records relating to the purchase or use of extracted cannabinoids:
 - (a) Name and license number of licensed processor from which the processor purchased the material;
 - (b) If the licensed hemp processor is from a state or jurisdiction other than Ohio, the originating state or jurisdiction, the processor's address, and a copy of their last inspection report;
 - (c) A bill of sale or other document that indicates the purchase price, purchased quantity, and date of purchase.
 - (d) The certificate of analysis from the testing laboratory which meets the requirements of rule 901:14-2-14 which indicates that the material meets the definition of hemp and hemp product as outlined in rule 901:14-2-15.
- (3) Records relating to the extraction process:
 - (a) The operational plan as required by rule 901:14-2-11;
 - (b) Records showing that the extraction method utilized meets the requirements of rule 901:14-2-12; and
 - (c) All applicable fire, safety, and building code documents and inspection reports.
- (4) Certificate of analysis as required by rule 901:14-2-13.
- (5) Records relating to disposal as required by rule 901:14-2-16.

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(B) A processor may use an electronic system for the storage and retrieval of records required by this rule and chapter. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this rule.

901:14-2-19 Prohibited products.

(A) The following products shall not be offered for sale:

(1) Any hemp product which exceeds the acceptable hemp THC level.

(2) All hemp products contained in a batch or lot which via laboratory testing:

(a) Fails to satisfy the standards set forth in Table 9 of the "Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control" (2014) monograph.

(b) For the purposes of mycotoxin contamination analysis:

(i) The total of the detected amounts, if any, of aflatoxin B1, aflatoxin B2, aflatoxin G1, and aflatoxin G2 exceeds twenty micrograms per kilogram; and

(ii) The detected amount, if any, of ochratoxin A exceeds twenty micrograms per kilogram.

(c) For the purposes of heavy metal contamination analysis:

(i) The detected amount of arsenic, if any, exceeds 0.42 parts per million.

(ii) The detected amount of cadmium, if any, exceeds 0.27 parts per million.

(iii) The detected amount of lead, if any, exceeds 0.87 parts per million.

(iv) The detected amount of mercury, if any, exceeds 0.87 parts per million.

(d) For the purposes of pesticide residue analysis, fails to satisfy the most stringent acceptable standard for an approved pesticide chemical residue in a food item as set forth in 40 C.F.R. Part 180, as effective on September 8, 2017.

(3) Any hemp product that was produced in violation of Chapter 928 of the Revised Code or the rules of this chapter.

(B) Any prohibited product, as well as all products in their corresponding batch or lot, as outlined in paragraph (A) of this rule shall be immediately destroyed by the processor.

901:14-2-20 Notice of adulteration or misbranding.

(A) Whenever the director of agriculture finds or has cause to believe, that any hemp product is adulterated or so misbranded as to be dangerous or fraudulent, within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, the director shall affix to the hemp product a tag or other appropriate marking, giving notice that the hemp product is, or is suspected of being, adulterated or misbranded, and has been detained or embargoed, and warning all persons not to remove or dispose of the hemp product by sale or otherwise until permission for removal or disposal is given by the director.

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(B) When a hemp product detained or embargoed has been found by the director to be adulterated or misbranded, the director shall petition the municipal or county court in whose jurisdiction the hemp product is detained or embargoed for an order for condemnation of the hemp product.

(C) If the court finds that a hemp product is adulterated or misbranded, the hemp product shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of the director, and all court costs, fees, storage, and other proper expenses shall be taxed against the claimant of the hemp product or the claimant's agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the hemp product, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond as ordered by the court, conditioned that the hemp product shall be so labeled or processed, has been executed, may by order direct that the hemp product be delivered to the claimant thereof for labeling or processing under the supervision of the director. The expense of supervision shall be paid by the claimant. The bond shall be returned to the claimant of the hemp product on representation to the court by the director that the hemp product is no longer in violation of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, and that the expenses of supervision have been paid.

901:14-2-21 Cooperation with law enforcement and other federal agencies.

(A) The department shall provide information about approved processing, handling, and storage site locations to representatives of the United States department of agriculture (USDA), and any federal, state, or local law enforcement agency whose representatives request licensed site information, including GPS coordinates.

(B) Immediately upon request, licensees shall produce a copy of his or her license to a representative of the department or a law enforcement agency.

901:14-2-99 Enforcement.

(A) The director shall deny, suspend, or revoke a hemp processing license if the licensed processor or applicant has:

(1) Provided false or misleading information on the hemp processing application or renewal application;

(2) Not complied with the background check requirements as outlined in rule 901:14-2-05 of the Administrative Code;

(3) Plead guilty to or was convicted of a felony relating to a controlled substance within the last ten years; and

(4) Negligently violated section 928.04 of the Revised Code or the rules of this chapter three or more times in any five-year period.

(B) If the director determines that a licensed processor has negligently violated a provision in Chapter 928 of the Revised Code or the rules of this chapter, the director shall issue a corrective action plan to the licensed processor. The director shall include in the corrective action plan both of the following:

(1) A reasonable date by which the licensed processor shall correct the violation; and

(2) A requirement that the licensed processor shall report to the director regarding the licensed processor's compliance with the requirements of this chapter, rules adopted under it, and the corrective action plan

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for two calendar years immediately following the date of the violation.

- (C) The director may suspend or revoke a hemp processing license if the licensee has failed to comply with Chapter 928 of the Revised Code or the rules of this chapter.
- (D) If the director has or proposed to have denied, suspended, or revoked a hemp processing license, the licensed processor or applicant shall be afforded a hearing in accordance with Chapter 119 of the Revised Code.