AN ACT relating to medicinal hemp products and declaring an emergency.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 260.850 is amended to read as follows:

As used in KRS 260.850 to 260.869:

(1) ***"Batch" means a specific quantity of medicinal hemp product that is uniform, intended to meet specifications for identity, purity, strength, and composition, and produced during a specified time period according to a single manufacturing record during the same cycle of manufacture;***

(2) "Batch number" means a distinctive group of letters, numbers, or symbols, or any combination thereof, from which the complete history of the processing, manufacturing, packaging, labeling, and holding of a batch of medicinal hemp product can be determined, including but not limited to:

(a) Source of the hemp material;

(b) Cultivation inputs used, including fertilizers, pesticides, soil amendments, and water sources;

(c) Manufacturing date and location;

(d) Laboratory test results;

(e) Distribution records; and

(f) Any remediation processes applied, including methods, materials used, and rationale;

(3) "Commissioner" means the Commissioner of the Kentucky Department of Agriculture;

(4) ~~[(2)]~~ "Cultivating" means planting, growing, and harvesting a plant or crop;

(5) ~~[(3)]~~ "Department" means the Kentucky Department of Agriculture;

(6) ~~[(4)]~~ "Handling" means possessing or storing hemp for any period of time on premises owned, operated, or controlled by a person licensed to cultivate or process hemp. "Handling" also includes possessing or storing hemp in a vehicle for any

period of time other than during its actual transport from the premises of a licensed person to cultivate or process hemp to the premises of another licensed person;

(7)~~[(5)]~~ "Hemp" or "industrial hemp":

(a) 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 of one percent (0.3%) on a dry weight basis; and

(b) Does not include medicinal cannabis as defined in KRS 218B.010;

(8)~~[(6)]~~ "Hemp products" or "industrial hemp products":

(a) Means products derived from, or made by, processing hemp plants or plant parts;~~[and]~~

(b) ***Includes medicinal hemp products; and***

(c) Does not include medicinal cannabis products as defined in KRS 218B.010;

(9) "Individual biological variability" means differences in individual human response to hemp-derived products based on genetic, metabolic, dietary, environmental, age-related, hormonal, medication-interaction, or health-related factors;

(10)~~[(7)]~~ "Licensee" means an individual or business entity possessing a license issued by the department under the authority of this chapter to grow, handle, cultivate, process, or market hemp or hemp products;

(11)~~[(8)]~~ "Marketing" means promoting or selling a product within the Commonwealth, in another state, or outside of the United States. "Marketing" includes efforts to advertise and gather information about the needs or preferences of potential consumers or suppliers;

(12) "Medical grade" means a market-based quality designation indicating compliance with enhanced manufacturing, testing, and labeling standards

established in Section 2 of this Act;

(13) "Medicinal hemp product":

(a) Means a nonintoxicating dietary supplement intended for human consumption that:

1. Is derived from, or made by, processing hemp;

2. Contains only naturally occurring cannabinoids, terpenes, and flavonoids; and

3. Has a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry-weight basis; and

(b) Does not include:

1. Any cannabinoids that are not naturally found or produced in hemp;

2. Cannabinoids that are synthesized outside of the plant; or

3. Medicinal cannabis as defined in KRS 218B.010;

(14) "Natural agricultural variability"

(a) Means differences in cannabinoid, terpene, flavonoid, mineral, or other constituent profiles resulting from lawful agricultural practices, soil composition, climate, cultivar selection, water source, or harvest timing; and

(b) Is inherent to agriculture and shall not be construed as adulteration, contamination, or noncompliance;

(15) ~~[(9)]~~ "Processing" means converting an agricultural commodity into a marketable form;

(16) "Purity of production" means the integrity and transparency of cultivation and processing practices, including soil composition, water sources, cultivation inputs, and postharvest handling, recognizing that agricultural context influences product chemistry;

(17) "Population-level harm" means documented, reproducible evidence of adverse

health outcomes affecting a significant portion of consumers beyond isolated incidents or anecdotal reports;

(18) "Remediation":

(a) Means any postharvest chemical or physical process used to reduce, remove, or alter contaminants or naturally occurring constituents of hemp; and

(b) Includes but is not limited to dilution, chemical treatment, chromatography, distillation, or other processes applied after harvest to modify product composition; and

(19) ~~[(10)]~~ "University" means an accredited institution of higher education located in the Commonwealth.

➔SECTION 2. A NEW SECTION OF KRS 260.850 TO 260.869 IS CREATED TO READ AS FOLLOWS:

(1) Each batch of medicinal hemp product shall be assigned a specific batch number by the processor. Batch records shall be maintained for a minimum of three (3) years and shall be made available to the department upon request.

(2) (a) Each batch shall undergo independent testing to determine:

1. Cannabinoid profile;

2. Compliance with delta-9 tetrahydrocannabinol concentration restrictions as established in KRS 260.850 to 260.869; and

3. The presence or absence of:

a. Pesticides;

b. Microbial contaminants;

c. Residual solvents; or

d. Mycotoxins.

(b) Testing shall be performed by a lab that:

1. Is not owned, operated, or financially controlled by the manufacturer

of the product being tested;

2. Is accredited to ISO/IEC 17025 standards as established by the International Organization for Standardization;

3. Has demonstrated proficiency in cannabis and hemp testing; and

4. Maintains accountability for accuracy, methodological integrity, and transparency in testing practices;

(c) Natural agricultural variability in raw hemp material shall not be deemed adulteration, contamination, or noncompliance;

(d) Producers shall not be penalized for documented laboratory error or misconduct beyond their control;

(e) Results of independent testing shall be made publicly accessible through electronic means by the processor. Publicly available results shall include:

1. Batch number;

2. Date of testing;

3. Laboratory name and accreditation;

4. Results for all required testing parameters;

5. Whether the product passed or failed;

6. Notation if the product was derived from remediated hemp material; and

7. A statement acknowledging natural agricultural variability; and

(f) Medicinal hemp product processors, handlers, or marketers shall not be held liable for documented laboratory error or misconduct beyond their control.

(3) Each medicinal hemp product packaged for retail sale shall have affixed to its label:

(a) The product's identity as a hemp-derived product, including whether the processor designates the product as medical grade;

(b) The batch number of all batches of medicinal hemp product within the container;

(c) In clearly legible and conspicuous form, language identifying the product's intended use as a dietary supplement;

(d) The product's cannabinoid content per serving;

(e) The product's cannabinoid profile, including the product's percentage of tetrahydrocannabinol and cannabidiol contents;

(f) Contact information for the manufacturer;

(g) An ingredient list;

(h) An expiration date;

(i) A scannable quick response (QR) code or web address that provides direct access to the batch-specific details;

(j) A disclosure indicating if the product has been subject to remediation; and

(k) Any required federal disclaimers, including but not limited to:

1. "This product has not been evaluated by the Food and Drug Administration";

2. "This product is not intended to diagnose, treat, cure, or prevent any disease"; and

3. "Individual results may vary based on biological, dietary, and lifestyle factors".

(4) A medicinal hemp product shall not, through marketing and advertising or directly on the product's label:

(a) Claim the product is intended to treat any disease;

(b) Claim the product is available through prescription only;

(c) Be marketed directly or indirectly to minors, including but not limited to marketing and product containers substantially resembling existing candy or candy products; or

(d) Make false or misleading claims, including but not limited to:

1. Misrepresenting the cannabinoid profile in the product;

2. Overstating or understating the cannabinoid content beyond an acceptable variance range of higher or lower than ten percent (10%);

3. Making false claims regarding organic certification or production methods; or

4. Failing to disclose remediation when required.

(5) Any product regulated under this section, including any product designated as medical grade, shall not require a prescription, physician authorization, or physician recommendation.

(6) The department shall not establish, maintain, or require participation in any patient registry, consumer database, or tracking system for the purchase of medicinal hemp products, including those designated as medical grade.

➔Section 3. KRS 260.862 is amended to read as follows:

(1) In addition to any other powers vested in it by law, the department shall have the authority and power to promulgate administrative regulations ***in accordance with KRS Chapter 13A*** to:

(a) License persons who wish to cultivate, handle, process, or market hemp;

(b) ***License persons who wish to handle, process, or market medicinal hemp products, but the department shall not limit the number of medicinal hemp product licenses;***

(c) Prescribe rules for a university's participation in, or affiliation with, any hemp program;

(d) ~~[(c)]~~ Prescribe sampling and testing procedures to ensure that hemp and hemp products cultivated, handled, processed, or marketed under the authority of ***KRS 260.850 to 260.869*** ~~[this section]~~ do not exceed the concentration levels defined in federal law as it currently exists or as it may be subsequently

amended;

(e)~~[(d)]~~ Define classes or categories of hemp products that are eligible for sale, transfer, or distribution to members of the public;~~[and]~~

(f)~~[(e)]~~ Establish a schedule of nonrefundable fees for applicants and licensees***;***

and

(g) 1. Establish quality and safety standards for the handling, processing, or marketing of medicinal hemp products, including tracking and auditing procedures for batches of medicinal hemp products, including standards applicable to products designated as medical grade.

2. In developing quality and safety standards, the department shall:

a. Consider diverse sources of evidence, including agronomic science, real-world use data, independently replicated studies, and traditional agriculture practices;

b. Consider funding sources and conflicts of interest for relied-upon research;

c. Avoid reliance solely on speculative risk, isolated studies, or industry-dominated research absent demonstrable population-level harm;

d. Distinguish natural agricultural variability from adulteration or contamination;

e. Acknowledge individual biological variability in evaluating adverse event reports or consumer feedback; and

f. Consider the impact of proposed standards on small farmer viability and market competition.

3. In developing quality and safety standards, the department shall not:

a. Penalize producers for natural agricultural variability or

documented laboratory error;

b. Favor large-scale remediation operations over quality agricultural products;

c. Impose compliance barriers designed to consolidate market power or exclude small farmers; or

d. Expand regulatory authority beyond the explicit boundaries established in KRS 260.850 to 260.869.~~[.]~~

(2) (a) ***The department shall have exclusive authority over the regulation of the processing, handling, manufacturing, and licensing of medicinal hemp products.***

(b) In evaluating applications for medicinal hemp products licenses, the department shall give priority to:

1. Existing licensed hemp growers and processors;

2. Kentucky-based agricultural operations and family farms;

3. Applicants with demonstrated experience in hemp cultivation or agricultural commodity production;

4. Applicants whose business plans emphasize purity of production and minimal remediation; and

5. Applicants whose business plans promote rural economic development and job creation in Kentucky.

(c) The department shall not impose license caps, exclusive of licenses, or requirements that favor vertical integration or large-scale operators over small farms and family farms.

(3) (a) A person shall not~~[No person shall]~~ cultivate, handle, process, or market hemp in the Commonwealth unless the person holds a license issued by the department.

(b) Any person seeking to cultivate hemp shall provide to the department the

legal description and global positioning coordinates sufficient for locating the fields or greenhouses to be used to grow hemp.

(c) Any person seeking to cultivate or process hemp ***or medicinal hemp products*** shall provide to the department prior written consent allowing representatives of the department, the Department of Kentucky State Police, and other state and local law enforcement agencies to enter onto all premises where hemp ***or hemp products are*** ~~[is]~~ cultivated, processed, or stored for the purpose of conducting physical inspections or ensuring compliance with the requirements of KRS 260.850 to 260.869 and administrative regulations promulgated by the department.

(d) An applicant for a license issued by the department shall submit to and pay for an annual criminal background check conducted by the Department of Kentucky State Police or another state or federal law enforcement agency or another entity selected by the department.

(e) ***A person*** ~~[No person]~~ who has been convicted of any felony or any drug-related misdemeanor or violation in the previous ten (10) years from the date of application shall ***not*** be eligible to obtain a license, provided, however, that:

1. A person who was growing hemp lawfully with a license, registration, or authorization under a pilot program authorized by Section 7606 of the Agricultural Act of 2014, 7 U.S.C. sec. 5940, shall be eligible to obtain a license to grow hemp; and
2. A person who was lawfully growing hemp under Section 7606 of the Agricultural Act of 2014 before December 20, 2018, and was convicted prior to December 20, 2018, shall be eligible to obtain a license to grow hemp.

(f) Any person seeking to handle or process a medicinal hemp product shall

comply with current good manufacturing, packaging, labeling, or holding practices as defined in 21 C.F.R. pt. 111.

➔Section 4. This Act may be cited as the Kentucky Medicinal Hemp Farmers Act.

➔Section 5. Whereas it is imperative that Kentucky's hemp cultivators, processors, handlers, and marketers are capable of producing medicinal hemp products, including products designated as medical grade, within the growing season and are prepared to participate promptly if any federal purchasing, reimbursement, or demonstration pathway applicable to hemp-derived products becomes available, an emergency is declared to exist, and this Act takes effect upon its passage and approval by the Governor or upon its otherwise becoming a law.