AM381 LB230 CSO - 02/21/2025

AMENDMENTS TO LB230

(Amendments to Standing Committee amendments, AM55)

Introduced by Hallstrom, 1.

- 1 1. Strike the original sections and all amendments thereto and
- 2 insert the following new sections:
- 3 **Section 1.** Sections 1 to 15 of this act shall be known and may be
- 4 cited as the Kratom Consumer Protection Act.
- 5 Sec. 2. For purposes of the Kratom Consumer Protection Act:
- 6 (1) Attractive to children means products:
- 7 (a) Manufactured in the shape of humans, cartoons, or animals; or
- 8 (b) Manufactured in a form that bears any reasonable resemblance to
- 9 an existing candy product that is familiar to the public as a widely
- 10 <u>distributed or a branded food product such that a product could be</u>
- 11 mistaken for the branded food product, especially by children;
- 12 (2) Department means the Department of Revenue;
- 13 (3) Kratom means the plant mitragyna speciosa or any part of that
- 14 plant, including, but not limited to, all components present in the
- 15 <u>natural plant;</u>
- 16 (4) Kratom extract means the material obtained by extraction of
- 17 kratom leaves with a solvent consisting of water, ethanol, or food-grade
- 18 carbon dioxide, or any other solvent allowed by federal or state
- 19 <u>regulation to be used in manufacturing a food ingredient;</u>
- 20 <u>(5) Kratom product means a food, ingredient, or dietary supplement</u>
- 21 that:
- 22 (a) Consists of or contains kratom or kratom extract;
- 23 (b) Does not contain any synthesized kratom alkaloids, other
- 24 synthesized kratom constituents, or synthesized metabolites of any kratom
- 25 constituent;
- 26 (c) Does not contain a level of 7-hydroxymitragynine in the alkaloid

1 fraction that is greater than two percent of the alkaloid composition of

- 2 the kratom product; and
- 3 <u>(d) Does not include any kratom product in any form that is</u>
- 4 combustible, intended to be used for vaporization, or is injectable;
- 5 (6) Processor means a person that manufacturers, packages, labels,
- 6 or distributes kratom products or advertises, represents, or holds itself
- 7 out as manufacturing, preparing, packaging, labeling, or distributing
- 8 <u>kratom products;</u>
- 9 (7) Retailer has the same meaning as in section 77-2701.32; and
- 10 <u>(8) Synthesized means an alkaloid or alkaloid derivative that has</u>
- 11 been created, in full or in part, by directed chemical, physical, or
- 12 <u>biosynthetic conversion, including, but not limited to, fermentation,</u>
- 13 <u>recombinant techniques</u>, <u>yeast-derived</u>, <u>or enzymatic techniques</u>, <u>rather</u>
- 14 than traditional food preparation techniques, such as heating or
- 15 <u>extracting</u>.
- 16 **Sec. 3.** (1) No person shall sell, offer for sale, provide, or
- 17 <u>distribute a kratom product to a person under twenty-one years of age.</u>
- 18 (2) An online retailer or marketplace that sells or offers for sale
- 19 <u>a kratom product shall implement an age-verification system to ensure</u>
- 20 compliance with this section.
- 21 Sec. 4. No person shall produce, manufacture, distribute, offer for
- 22 <u>sale, sell, or introduce into commerce a kratom product in the State of</u>
- 23 Nebraska if the product is manufactured in a manner that is attractive to
- 24 <u>children.</u>
- 25 **Sec. 5.** A kratom product sold, offered for sale, or introduced into
- 26 <u>commerce in the State of Nebraska shall:</u>
- 27 (1) Be manufactured, packaged, labeled, or held in a facility that
- 28 meets the requirements of 21 C.F.R. Part 111, as such regulations existed
- 29 <u>on January 1, 2025; and</u>
- 30 (2) Be manufactured, processed, packed, or held by a processor who
- 31 <u>has registered with the federal Food and Drug Administration as a food</u>

- 1 facility.
- 2 Sec. 6. A kratom product sold, offered for sale, or introduced into
- 3 commerce in the State of Nebraska shall have a label on each retail
- 4 package that clearly and conspicuously provides the following
- 5 <u>information:</u>
- 6 (1) The product is not recommended for use by individuals who are
- 7 under twenty-one years of age, who are pregnant, or who are
- 8 breastfeeding;
- 9 (2) A health care practitioner should be consulted prior to using
- 10 the product;
- 11 (3) The product may be habit-forming;
- 12 (4) The following statements: "These statements have not been
- 13 <u>evaluated by the Food and Drug Administration</u>. This product is not
- 14 <u>intended to diagnose, treat, cure, or prevent any disease.";</u>
- 15 (5) The name and place of business of the processor;
- 16 (6) Directions for use that include a recommended amount of the
- 17 <u>kratom product per serving that is:</u>
- 18 (a) Clearly described on the label for product forms such as
- 19 capsules, gummies, prepackaged, single-serving units, and similar product
- 20 forms; or
- 21 (b) A clear instruction or a mark on the package or container for
- 22 <u>beverages or liquids;</u>
- 23 (7) A recommended number of servings that can be safely consumed in
- 24 <u>a twenty-four-hour period;</u>
- 25 (8) A listing of the servings per container; and
- 26 (9) A listing of kratom alkaloids mitragynine and 7-
- 27 hydroxymitragynine and other ingredients in the product, including
- 28 quantitative declarations of the amount per serving of mitragynine.
- 29 Sec. 7. (1) The department shall establish, operate, and administer
- 30 <u>a program to register kratom products. The Tax Commissioner shall</u>
- 31 <u>designate an implementation date for such program which date is on or</u>

AM381 AM381 LB230 LB230 CSO - 02/21/2025 CSO - 02/21/2025

- 1 before January 1, 2026.
- 2 (2) Beginning on the implementation date designated by the Tax
- 3 <u>Commissioner pursuant to subsection (1) of this section:</u>
- 4 (a) No processor may manufacture, package, label, or distribute a
- 5 kratom product to be offered for sale in the State of Nebraska unless the
- 6 product has been registered with the department;
- 7 (b) Applications for product registration shall be submitted on a
- 8 form prescribed by the department. Each application shall include:
- 9 (i) The name, address, and state of organization for the processor
- 10 of the product;
- 11 (ii) A principal point of contact for the processor and contact
- 12 <u>information for the point of contact;</u>
- 13 <u>(iii) The name of the product;</u>
- 14 <u>(iv) The product label;</u>
- 15 (v) A certificate of analysis for the kratom product that states the
- 16 kratom product's alkaloid content and certifies that the kratom product
- 17 <u>has a level of 7-hydroxymitragynine that is less than two percent of the</u>
- 18 alkaloid composition of the kratom product from an independent
- 19 <u>laboratory</u>. Such laboratory shall obtain and maintain an International
- 20 Organization for Standardization and International Electrotechnical
- 21 <u>Commission (ISO/IEC) 17025 accreditation for testing and calibration</u>
- 22 <u>laboratories from an accreditation body that is a signatory to the</u>
- 23 International Laboratory Accreditation Cooperation Mutual Recognition
- 24 <u>Arrangement;</u>
- 25 (vi) A valid good manufacturing practice certificate issued by an
- 26 <u>accredited third-party certification body in compliance with 21 C.F.R.</u>
- 27 <u>Part 111; and</u>
- 28 (vii) A current food facility registration certificate issued by the
- 29 <u>federal Food and Drug Administration for all facilities where kratom</u>
- 30 products are manufactured, prepared, packaged, or labeled;
- 31 (c) A certificate of registration shall be valid for one calendar

AM381 LB230 LB230 CSO - 02/21/2025 CSO - 02/21/2025

- 1 year after the date of issue and shall not be transferable; and
- 2 <u>(d) The department may charge a fee for product registration</u>
- 3 applications and may adjust such fee annually. The fee shall be
- 4 <u>reasonable and shall not exceed any reasonable or necessary costs to</u>
- 5 <u>administer the Kratom Consumer Protection Act.</u>
- 6 (e) A product that contains the same kratom ingredients in the same
- 7 kratom delivery form, but is packaged, sold, or offered for sale in a
- 8 <u>different container, package, or volume shall be included in a single</u>
- 9 <u>registration</u>.
- 10 <u>(3) If an application is incomplete or deficient, the department</u>
- 11 shall, in a timely manner, notify the applicant in writing describing the
- 12 <u>reason or reasons and request additional information. If such application</u>
- 13 <u>is not corrected or supplemented within thirty days after the</u>
- 14 <u>department's request, the department shall deny the application.</u>
- 15 (4) If any false statement is made in any part of an application,
- 16 the department shall deny the application.
- 17 <u>(5) A person aggrieved by the denial of an application may request a</u>
- 18 <u>hearing pursuant to section 11 of this act.</u>
- 19 (6) A processor or retailer is not prohibited from selling,
- 20 preparing, manufacturing, distributing, maintaining, advertising,
- 21 representing, or holding itself out as selling, preparing, or maintaining
- 22 kratom products in the State of Nebraska prior to the implementation date
- 23 <u>designated</u> by the Tax Commissioner pursuant to subsection (1) of this
- 24 section, or while the first product registration applications submitted
- 25 by processors operating in the State of Nebraska as of January 1, 2025,
- 26 <u>are pending approval or denial by the department.</u>
- 27 **Sec. 8.** Beginning on the implementation date designated by the Tax
- 28 Commissioner pursuant to subsection (1) of section 7 of this act, the
- 29 <u>department shall make public a list of all registered kratom products on</u>
- 30 <u>its website.</u>
- 31 Sec. 9. (1) No person shall sell, offer for sale, provide, or

AM381 LB230 LB230 CSO - 02/21/2025 CSO - 02/21/2025

1 <u>distribute an adulterated kratom product in the State of Nebraska.</u>

- 2 (2) A product shall be deemed adulterated if:
- 3 (a) It contains any kratom alkaloid or metabolite, including 7-
- 4 hydroxymitragynine, and does not meet the definition of a kratom product
- 5 <u>under section 2 of this act; or</u>
- 6 <u>(b) The kratom product is combined with a dangerous nonkratom</u>
- 7 substance that contains a poisonous or otherwise deleterious nonkratom
- 8 ingredient, including, but not limited to, any substance listed as a
- 9 controlled substance under the laws of this state or federal law.
- 10 <u>(3) Upon receipt of evidence that suggests a product may be an</u>
- 11 <u>adulterated kratom product, the department may require the person</u>
- 12 <u>selling, providing, or distributing the product to obtain an independent</u>
- 13 third-party test of the product by a laboratory of the department's
- 14 choosing.
- 15 Sec. 10. (1) Any processor or retailer that violates any section of
- 16 the Kratom Consumer Protection Act, including those related to the
- 17 application or registration, or any of the rules and regulations adopted
- 18 and promulgated by the department that apply to processors or kratom
- 19 products shall be subject to the penalties provided in this section.
- 20 (2) For the first violation, the department shall impose a civil
- 21 penalty of up to one thousand dollars. For the second violation, the
- 22 department shall impose a civil penalty of up to five thousand dollars.
- 23 For a third violation and any subsequent violations, the department shall
- 24 impose a civil penalty of at least five thousand dollars and no more than
- 25 twenty thousand dollars and, if the violator is a processor, the
- 26 <u>department shall prohibit the sale of any kratom products of such</u>
- 27 processor within the State of Nebraska for a period of three years.
- 28 (3) For any processor or retailer that has no violation for a period
- 29 <u>of four consecutive years, a new violation shall be treated as a first</u>
- 30 <u>violation</u>.
- 31 (4) No determination that a violation has occurred shall be made

AM381 AM381 LB230 CSO - 02/21/2025 CSO - 02/21/2025

until notice has been given and a hearing has been held by the Tax 1

- 2 Commissioner as provided in section 11 of this act if requested by the
- 3 processor or retailer.
- (5) A retailer shall not be found to be in violation of the Kratom 4
- 5 Consumer Protection Act if it is shown by a preponderance of the evidence
- that the retailer relied in good faith upon the representation of a 6
- 7 processor that a product is not an adulterated kratom product as defined
- 8 in section 9 of this act or otherwise conformed to the act.
- 9 Sec. 11. (1) A processor or retailer aggrieved by a notice of
- denial of an application issued under section 7 of this act or a notice 10
- 11 of violation issued under section 10 of this act may request a hearing.
- 12 (2) Such request shall be made within twenty days after the receipt
- 13 of any such notice.
- 14 (3) At such hearing the Tax Commissioner, or any officer or employee
- 15 of the Tax Commissioner designated in writing, may examine any books,
- 16 papers, memoranda, or other evidence bearing upon the matter at issue and
- 17 require the attendance of any officer or employee of the processor or
- retailer or any person having knowledge pertinent to such hearing. The 18
- 19 Tax Commissioner or the Tax Commissioner's designee may administer oaths
- 20 to persons testifying at such hearing.
- 21 (4) During the hearing, the Tax Commissioner or the Tax
- 22 Commissioner's designee shall not be bound by the technical rules of
- 23 evidence, and no informality in any proceeding or in the manner of taking
- 24 testimony shall invalidate any order or decision made or approved by the
- 25 Tax Commissioner.
- 26 (5) Within a reasonable time after the hearing the Tax Commissioner
- 27 shall make a final decision or final determination and notify the
- 28 processor or retailer by mail of such decision or determination.
- 29 (6) If it is determined that a processor intentionally and
- 30 materially falsified any information contained in an application under
- 31 the Kratom Consumer Protection Act, the processor shall be ineligible to

1 <u>obtain a certification of registration for a period of twelve months</u>

- 2 <u>after the date of such determination.</u>
- 3 (7) A processor or retailer may appeal the decision of the Tax
- 4 <u>Commissioner</u>, and the appeal shall be in accordance with the
- 5 Administrative Procedure Act.
- 6 **Sec. 12.** The Attorney General shall have authority to enforce the
- 7 Kratom Consumer Protection Act pursuant to the Consumer Protection Act
- 8 and the Uniform Deceptive Trade Practices Act. This section shall not be
- 9 construed to allow for a private right of action under the Kratom
- 10 <u>Consumer Protection Act even though such action is authorized under the</u>
- 11 Consumer Protection Act and the Uniform Deceptive Trade Practices Act.
- 12 Sec. 13. (1) If a registered processor has been convicted by any
- 13 court of a violation of the Kratom Consumer Protection Act, the processor
- 14 may, in addition to the penalties for such offense, incur a forfeiture of
- 15 the certificate of registration for its kratom products and all money
- 16 that had been paid for such certificate of registration.
- 17 <u>(2) If any materially false statement is made in any part of an</u>
- 18 application submitted under section 7 of this act, the applicant shall be
- 19 <u>subject to prosecution for perjury and if convicted may, in addition to</u>
- 20 the penalties for such offense, incur a forfeiture of any certificate of
- 21 registration that was issued for the applicant's kratom products and all
- 22 money that had been paid for such certificate of registration.
- 23 **Sec. 14.** Except as otherwise provided in the Kratom Consumer
- 24 <u>Protection Act, no political subdivision shall impose additional</u>
- 25 restrictions on the manufacturing, packaging, labeling, distribution, or
- 26 <u>sale of kratom products greater than or in addition to those enumerated</u>
- 27 <u>in the act.</u>
- 28 Sec. 15. The department may adopt and promulgate rules and
- 29 regulations to carry out the Kratom Consumer Protection Act.
- 30 **Sec. 16.** This act becomes operative on July 1, 2025.
- 31 Sec. 17. Since an emergency exists, this act takes effect when

AM381 LB230 CSO - 02/21/2025 CSO - 02/21/2025

1 passed and approved according to law.