LEGISLATURE OF NEBRASKA ONE HUNDRED NINTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 230

Introduced by Hallstrom, 1.

Read first time January 14, 2025

Committee:

- 1 A BILL FOR AN ACT relating to kratom; to adopt the Kratom Consumer
- 2 Protection Act; to provide an operative date; and to declare an
- 3 emergency.
- 4 Be it enacted by the people of the State of Nebraska,

Section 1. Sections 1 to 16 of this act shall be known and may be

- 2 cited as the Kratom Consumer Protection Act.
- 3 **Sec. 2.** For purposes of the Kratom Consumer Protection Act:
- 4 (1) Attractive to children means products:
- 5 (a) Manufactured in the shape of humans, cartoons, or animals; or
- 6 (b) Manufactured in a form that bears any reasonable resemblance to
- 7 an existing candy product that is familiar to the public as a widely
- 8 distributed or a branded food product such that a product could be
- 9 mistaken for the branded food product, especially by children;
- 10 (2) Department means the Department of Revenue;
- 11 (3) Kratom extract means the material obtained by extraction of
- 12 <u>kratom leaves with a solvent consisting of water, ethanol, or food-grade</u>
- 13 <u>carbon dioxide</u>, <u>or any other solvent allowed by federal or state</u>
- 14 regulation to be used in manufacturing a food ingredient;
- 15 (4) Kratom leaf means any part of the leaf of the mitragyna speciosa
- 16 plant in a fresh, dehydrated, or dried form that has been subjected to no
- 17 post-harvest processing other than drying or size reduction, including,
- 18 <u>but not limited to, cutting, milling, or a similar procedure, and</u>
- 19 cleaning or sterilization through the application of heat, steam,
- 20 pressurization, irradiation, or other standard treatments applied to food
- 21 <u>ingredients;</u>
- 22 (5) Kratom product means a food, ingredient, or dietary supplement
- 23 that:
- 24 (a) Consists of or contains kratom leaf or kratom leaf extract;
- 25 (b) Does not contain any synthesized kratom alkaloids, other
- 26 <u>synthesized kratom constituents, or synthesized metabolites of any kratom</u>
- 27 constituent; and
- 28 (c) Does not contain a level of 7-hydroxymitragynine in the alkaloid
- 29 fraction that is greater than two percent of the alkaloid composition of
- 30 <u>the kratom product;</u>
- 31 (6) Processor means a person that manufacturers, packages, labels,

1 or distributes kratom products or advertises, represents, or holds itself

- 2 out as manufacturing, preparing, packaging, labeling, or distributing
- 3 kratom products;
- 4 (7) Retailer has the same meaning as in section 77-2701.32; and
- 5 (8) Synthesized means an alkaloid or alkaloid derivative that has
- 6 been created by chemical synthesis or biosynthetic means, including, but
- 7 not limited to, fermentation, recombinant techniques, or yeast-derived
- 8 <u>techniques</u>, rather than traditional food preparation techniques, such as
- 9 <u>heating or extracting.</u>
- 10 Sec. 3. (1) No person shall sell, offer for sale, provide, or
- 11 <u>distribute kratom leaf or a kratom product to a person under twenty-one</u>
- 12 <u>years of age.</u>
- 13 (2) An online retailer or marketplace that sells or offers for sale
- 14 <u>kratom leaf or a kratom product shall implement an age-verification</u>
- 15 system to ensure compliance with this section.
- Sec. 4. No person shall produce, manufacture, distribute, offer for
- 17 sale, sell, or introduce into commerce a kratom product in the State of
- 18 <u>Nebraska if the product is manufactured in a manner that is attractive to</u>
- 19 <u>children.</u>
- 20 Sec. 5. A kratom product sold, offered for sale, or introduced into
- 21 <u>commerce in the State of Nebraska shall:</u>
- 22 (1) Be manufactured, packaged, labeled, and held in compliance with
- 23 federal regulation for current good manufacturing practice in
- 24 manufacturing, packaging, labeling, or holding operations for dietary
- 25 supplements as codified in 21 C.F.R. Part 111, as such regulations
- 26 existed on January 1, 2025; and
- 27 <u>(2) Be manufactured, processed, packed, or held by a processor who</u>
- 28 has registered with the federal Food and Drug Administration as a food
- 29 <u>facility</u>.
- 30 Sec. 6. A kratom product sold, offered for sale, or introduced into
- 31 commerce in the State of Nebraska shall:

- 1 (1) Be labeled in compliance with all applicable federal food or
- 2 <u>dietary supplement labeling regulations, including, but not limited to,</u>
- 3 21 C.F.R. Part 101, as such regulations existed on January 1, 2025;
- 4 (2) Be labeled in compliance with all applicable federal retail
- 5 package labeling requirements for allergen labeling; and
- 6 (3) Have a label on each retail package that clearly and
- 7 conspicuously provides the following information:
- 8 (a) The product is not recommended for use by individuals who are
- 9 under twenty-one years of age, who are pregnant, or who are
- 10 breastfeeding;
- 11 (b) A health care practitioner should be consulted prior to using
- 12 the product;
- 13 <u>(c) The product may be habit-forming;</u>
- 14 (d) The following statements: "These statements have not been
- 15 <u>evaluated</u> by the federal Food and Drug Administration. This product is
- 16 not intended to diagnose, treat, cure, or prevent any disease.";
- (e) The name and place of business of the processor;
- 18 (f) Directions for use that include a recommended amount of the
- 19 <u>kratom product per serving that is:</u>
- 20 <u>(i) Clearly described on the label for product forms such as</u>
- 21 capsules, gummies, prepackaged, single-serving units, and similar product
- 22 forms; or
- 23 <u>(ii) A clear instruction or a mark on the package or container for</u>
- 24 beverages or liquids;
- 25 (g) A recommended number of servings that can be safely consumed in
- 26 <u>a twenty-four-hour period;</u>
- 27 (h) A listing of the servings per container;
- 28 (i) A listing of kratom alkaloids mitragynine and 7-
- 29 hydroxymitragynine and other ingredients in the product, including
- 30 quantitative declarations of the amount per serving of mitragynine; and
- 31 (j) A declaration that any level of 7-hydroxymitragynine does not

LB230 2025

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

- 2 <u>overall alkaloid composition of the product.</u>
- 3 Sec. 7. (1) The department shall establish, operate, and administer
- 4 a program to register kratom products. The Tax Commissioner shall
- 5 <u>designate an implementation date for such program which date is on or</u>
- 6 before January 1, 2026.
- 7 (2) Beginning on the implementation date designated by the Tax
- 8 <u>Commissioner pursuant to subsection (1) of this section:</u>
- 9 (a) No processor may manufacture, package, label, or distribute a
- 10 <u>kratom product to be offered for sale in the State of Nebraska unless the</u>
- 11 product has been registered with the department.
- 12 <u>(b) Applications for product registration shall be submitted on a</u>
- 13 form prescribed by the department. Each application shall include:
- 14 (i) The name, address, and state of organization for the processor
- 15 of the product;
- 16 (ii) A principal point of contact for the processor and contact
- 17 information for the point of contact;
- 18 (iii) The name of the product;
- 19 (iv) The product label;
- 20 (v) A certificate of analysis for the kratom product that states the
- 21 kratom product's alkaloid content and certifies that the kratom product
- 22 has a level of 7-hydroxymitragynine that is less than two percent of the
- 23 alkaloid composition of the kratom product from an independent
- 24 laboratory. Such laboratory shall obtain and maintain an ISO/IEC 17025
- 25 accreditation for testing and calibration laboratories from an
- 26 <u>accreditation body that is a signatory to the International Laboratory</u>
- 27 Accreditation Cooperation Mutual Recognition Arrangement;
- 28 (vi) A valid good manufacturing practice certificate issued by an
- 29 accredited third-party certification body in compliance with 21 C.F.R.
- 30 <u>Part 117; and</u>
- 31 (vii) A current food facility registration certificate issued by the

LB230 2025

1 federal Food and Drug Administration for all facilities where kratom

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

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

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

LB230 2025

1 obtain a certification of registration for a period of twelve months

- 2 <u>after the date of such determination.</u>
- 3 (3) A processor or retailer may appeal the decision of the Tax
- 4 Commissioner, and the appeal shall be in accordance with the
- 5 Administrative Procedure Act.
- 6 Sec. 13. 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 Consumer Protection Act even though such action is authorized under the
- 11 <u>Consumer Protection Act and the Uniform Deceptive Trade Practices Act.</u>
- 12 **Sec. 14.** (1) If a processor has been convicted by any court of a
- 13 violation of the Kratom Consumer Protection Act, the registered 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
- that had been paid for such certificate of registration.
- 17 (2) If any false statement is made in any part of an application
- 18 submitted under section 7 of this act, the applicant or applicants shall
- 19 <u>be subject to prosecution for perjury and if convicted may, in addition</u>
- 20 to the penalties for such offense, incur a forfeiture of any certificate
- 21 of registration that was issued for its kratom products and all money
- 22 that had been paid for such certificate of registration.
- 23 **Sec. 15.** Except as otherwise provided in the Kratom Consumer
- 24 Protection Act, no political subdivision shall impose additional
- 25 restrictions on the manufacturing, packaging, labeling, distribution, or
- 26 <u>sale of kratom leaves, kratom leaf extracts, or kratom products greater</u>
- 27 <u>than or in addition to those enumerated in the act.</u>
- 28 Sec. 16. The department may adopt and promulgate rules and
- 29 regulations to carry out the Kratom Consumer Protection Act.
- 30 **Sec. 17.** This act becomes operative on July 1, 2025.
- 31 Sec. 18. Since an emergency exists, this act takes effect when

1 passed and approved according to law.