

HB 2056
January 26 2021
Nick Reinecker
Proponent
Chairman: Rep. John Barker

House Federal and State Affairs

AN ACT concerning food products; relating to the Kansas food, drug

and cosmetic act; regulating the sale and distribution of kratom products; amending K.S.A. 65-656 and repealing the existing section.

Page 1 Line 6

Section 1. K.S.A. 65-656 is hereby amended to read as follow

Page 1 Line 12

(c) "Food" means: (1) Articles used for food or drink for humans or other animals; (2) chewing gum; and (3) articles used for components of any such article.

Page 1 Line 15

(d) (1) "Drug" means: (1)(A) Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; (2)(B) articles intended for use in diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; (3)(C) articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and (4)(D) articles intended for use as a component of any articles specified in paragraph (1), (2), or (3); but does not include devices or their components, parts or accessories subparagraph (A), (B) or (C).

Page 1 Line 26

(2) The term "drug" shall not include: (A) Devices or their components, parts or accessories; or (B) amygdalin (laetrile).

Laetrile/Amygdalin (PDQ®)—Patient Version - National Cancer Institute

<https://www.cancer.gov/about-cancer/treatment/cam/patient/laetrile-pdq>

Apr 5, 2018 — Laetrile is a compound that has been used as a treatment for people with cancer. Laetrile is another name for amygdalin. Amygdalin is a bitter substance found in fruit pits, such as apricots, raw nuts, lima beans, clover, and sorghum. It makes hydrogen cyanide which is changed into cyanide when taken into the body.

Page 3 Line 4

(o) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

Page 3 Line 7

(p) (1) "Food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures, or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food, to be safe under the conditions of its intended use.

Page 3 Line 19

(2) "Food additive" does not include: (1)(A) A pesticide chemical in or on a raw agricultural commodity; (2)(B) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; (3)(C) a color additive; or (4)(D) any substance used in accordance with a sanction or approval granted prior to the enactment of the food additive amendment of 1958, pursuant to the federal act. (q) (1) "Color additive" means a material which that: (A) Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or (B) when added or applied to a food, drug or cosmetic, or to the human body or any part thereof, is capable, alone or through reaction with another substance, of imparting color thereto; except that such term. (2) The term "color additive" does not include any material which that has been or hereafter is exempted under the federal act. (2)(3) The term "color" includes black, white and intermediate grays. (3)(4) Nothing in this subsection shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

Page 4 Line 2

(r) "Imitation" means any article made in the semblance of another, consisting of similar or dissimilar ingredients and being capable of being substituted for the imitated article without the knowledge of the consumer.

Page 4 Line 5

(s) "Federal act" means the federal food, drug and cosmetic act, title 21 U.S.C. § 301 et seq., 52 Stat. 1040 et seq.

<https://www.deadiversion.usdoj.gov/21cfr/21usc/802.htm>

Title 21 United States Code (USC) Controlled Substances Act

SUBCHAPTER I — CONTROL AND ENFORCEMENT

Part A — Introductory Provisions

§802. Definitions

As used in this subchapter:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far

addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

(9) The term "depressant or stimulant substance" means—

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(12) The term "drug" has the meaning given that term by section 321(g)(1) of this title.

Page 5 Line 9-17

(ee) "Kratom dealer" means a person that manufactures, sells, prepares, produces, distributes or maintains kratom products, or advertises or represents that such person manufactures, sells, prepares, produces, distributes or maintains kratom products, including, but not limited to, a manufacturer, wholesaler, retail store, restaurant, hotel, catering facility, camp, bakery, delicatessen, grocery store, convenience store or nursing home.

(ff) "Kratom product" means a food containing any part of the plant mitragyna speciosa.

Page 9 Line 14

New Section 8 (c) In addition to any adulteration as described in K.S.A. 65-664, and amendments thereto, kratom products shall also be considered adulterated if such products contain:(1) A level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the alkaloid composition of such product.

There is no FDA requirement to list the precise amount of caffeine present in a product.

<https://www.fda.gov/food/food-additives-petitions/food-additive-status-list>

GRAS Generally recognized as safe

NAT Natural substances and extractives

SP Spices, other natural seasonings & flavoring

VET Veterinary drug, which may leave residue in edible tissues of animals or in edible animal products & flavorings

GMP In accordance with good manufacturing practices; or sufficient for purpose; or quantity not greater than required

REG Food additives for which a petition has been filed and a regulation issued.

NUTRS Nutritive Sweetener

Algae, brown (kelp), or red - NAT, GRAS, REG -184.1120, 184.1121 and 172.365

Aspartame - NUTRS, REG, GMP, Sweetening agent, sugar substitute uses stated in - 172.804. Sugar substitute tablets, breakfast cereals, chewing gum, dry bases for beverages, instant coffee and tea beverages, gelatins, puddings, fillings, and dairy product analog toppings, ready-to-serve nonalcoholic flavored beverages, tea beverages, fruit juice based drinks where food standards permit such use, fruit flavored drinks and ades, imitation fruit flavored drinks and ades, frozen

stick-type confections and novelties, breath mints, hard and soft candy, refrigerated ready-to-serve gelatins, puddings, and fillings, fruit wine beverages with EtOH <7%, yogurt-type products where aspartame is added after pasteurization and culturing, refrigerated flavored milk beverages, frozen desserts, frostings, toppings, fillings, glazes and icings for precooled baked goods, frozen, ready-to-thaw-and-eat cheesecakes, fruit and fruit toppings, frozen dairy and nondairy frostings, toppings, and fillings, fruit spreads, fruit toppings, and fruit syrups, malt beverages with <7% EtOH and containing fruit juice, baked goods and baking mixes 0.5 wt.-% of ready-to bake products or of finished formulation and prior to baking

<https://happilyunprocessed.com/food-additives/>

<https://ods.od.nih.gov/pubs/energydrinks2013/mattia.pdf>

When dealing with different substances like, cocoa, caffeine, cannabis, nicotine, and alcohol there is a need for consistency and equity. When these substances are of naturally occurring origin less restriction and control should always be a priority. Nonetheless, for the purposes of this hearing I would like to bring attention to naturally occurring caffeine substances and products and cannabis, regardless of quantitative or qualitative cannabinoid and/or caffeine content and ask that conceptual amendments would be considered that would put cannabis and its products in a status that allows maximum individual liberty similar to kratom, alcohol, tobacco, sugar and caffeine/coffee. In addition, I am concerned about the low percentage of active ingredient being proposed in this language that would then consider it to be adulterated.

Thank You
Nick Reinecker