

As Introduced

**135th General Assembly
Regular Session
2023-2024**

S. B. No. 103

Senator Blessing

A BILL

To amend sections 3715.01, 3715.99, 3717.01, and 1
3717.99 and to enact sections 3715.026 and 2
3717.34 of the Revised Code regarding sales of 3
kratom products. 4

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3715.01, 3715.99, 3717.01, and 5
3717.99 be amended and sections 3715.026 and 3717.34 of the 6
Revised Code be enacted to read as follows: 7

Sec. 3715.01. (A) As used in this chapter: 8

(1) "Person" means an individual, partnership, 9
corporation, or association. 10

(2) "Food" means: 11

(a) Articles used for food or drink for humans or animals; 12

(b) Chewing gum; 13

(c) Articles used for components of any such articles. 14

(3) "Drug" means: 15

(a) Articles recognized in the United States pharmacopoeia 16
and national formulary, or any supplement to them; 17

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; 18
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(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; 21
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(d) Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories. 24
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(4) "Device," except when used in division (B) (1) of this section and in division (A) (10) of section 3715.52, division (F) of section 3715.60, division (A) (5) of section 3715.64, and division (C) of section 3715.67 of the Revised Code, means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following: 27
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(a) Recognized in the United States pharmacopoeia and national formulary, or any supplement to them; 34
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(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or animals; 36
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(c) Intended to affect the structure or any function of the body of humans or animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or animals and is not dependent upon being metabolized for the achievement of any of its principal intended purposes. 39
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(5) "Cosmetic" means: 45

(a) Articles intended to be rubbed, poured, sprinkled, or 46
sprayed on, introduced into, or otherwise applied to the human 47
body or any part thereof for cleansing, beautifying, promoting 48
attractiveness, or altering the appearance; 49

(b) Articles intended for use as a component of any such 50
article, except that "cosmetic" does not include soap. 51

(6) "Label" means a display of written, printed, or 52
graphic matter upon the immediate container, exclusive of 53
package liners, of any article. 54

Any word, statement, or other information required by this 55
chapter to appear on the label must appear on the outside 56
container or wrapper, if any, of the retail package of the 57
article, or the label must be easily legible through the outside 58
container or wrapper. 59

(7) "Labeling" means all labels and other written, 60
printed, or graphic matter: 61

(a) Upon an article or any of its containers or wrappers; 62

(b) Accompanying such article. 63

(8) "Advertisement" means all representations disseminated 64
in any manner or by any means, other than by labeling, for the 65
purpose of inducing, or that are likely to induce, directly or 66
indirectly, the purchase of food, drugs, devices, or cosmetics. 67

(9) "New drug" means: 68

(a) Any drug the composition of which is such that the 69
drug is not generally recognized among experts qualified by 70
scientific training and experience to evaluate the safety of 71
drugs, as safe for use under the conditions prescribed, 72
recommended, or suggested in the labeling thereof; 73

(b) Any drug the composition of which is such that the 74
drug, as a result of investigation to determine its safety for 75
use under such conditions, has become so recognized, but that 76
has not, other than in an investigation, been used to a material 77
extent or for a material time under such conditions. 78

(10) "Contaminated with filth" applies to any food, drug, 79
device, or cosmetic that has not been protected as far as may be 80
necessary by all reasonable means from dust, dirt, and all 81
foreign or injurious substances. 82

(11) "Honey" means the nectar and saccharine exudation of 83
plants that has been gathered, modified, and stored in a 84
honeycomb by honeybees. 85

(12) "Finished dosage form" means the form of a drug that 86
is, or is intended to be, dispensed or administered to humans or 87
animals and requires no further manufacturing or processing 88
other than packaging, reconstituting, or labeling. 89

(13) (a) "Manufacture" means the planting, cultivating, 90
harvesting, processing, making, preparing, or otherwise engaging 91
in any part of the production of a drug by propagating, 92
compounding, converting, or processing, either directly or 93
indirectly by extracting from substances of natural origin, or 94
independently by means of chemical synthesis, or by a 95
combination of extraction and chemical synthesis, and includes 96
the following: 97

(i) Any packaging or repackaging of the drug or labeling 98
or relabeling of its container, the promotion and marketing of 99
the drug, and other activities incident to production; 100

(ii) The preparation and promotion of commercially 101
available products from bulk compounds for resale by pharmacies, 102

licensed health professionals authorized to prescribe drugs, or	103
other persons.	104
(b) "Manufacture" does not include the preparation,	105
compounding, packaging, or labeling of a drug by a pharmacist as	106
an incident to either of the following:	107
(i) Dispensing a drug in the usual course of professional	108
practice;	109
(ii) Providing a licensed health professional authorized	110
to prescribe drugs with a drug for the purpose of administering	111
to patients or for using the drug in treating patients in the	112
professional's office.	113
(14) "Dangerous drug" has the same meaning as in section	114
4729.01 of the Revised Code.	115
(15) "Generically equivalent drug" means a drug that	116
contains identical amounts of the identical active ingredients,	117
but not necessarily containing the same inactive ingredients,	118
that meets the identical compendial or other applicable standard	119
of identity, strength, quality, and purity, including potency,	120
and where applicable, content uniformity, disintegration times,	121
or dissolution rates, as the prescribed brand name drug and the	122
manufacturer or distributor holds, if applicable, either an	123
approved new drug application or an approved abbreviated new	124
drug application unless other approval by law or from the	125
federal food and drug administration is required.	126
No drug shall be considered a generically equivalent drug	127
for the purposes of this chapter if it has been listed by the	128
federal food and drug administration as having proven	129
bioequivalence problems.	130
(16) "Licensed health professional authorized to prescribe	131

drugs" and "prescriber" have the same meanings as in section 132
4729.01 of the Revised Code. 133

(17) "Home" means the primary residence occupied by the 134
residence's owner, on the condition that the residence contains 135
only one stove or oven used for cooking, which may be a double 136
oven, designed for common residence usage and not for commercial 137
usage, and that the stove or oven be operated in an ordinary 138
kitchen within the residence. 139

(18) "Potentially hazardous food" means a food that is 140
natural or synthetic, to which any of the following apply: 141

(a) It has a pH level greater than 4.6 when measured at 142
seventy-five degrees fahrenheit or twenty-four degrees celsius. 143

(b) It has a water activity value greater than 0.85. 144

(c) It requires temperature control because it is in a 145
form capable of supporting the rapid and progressive growth of 146
infectious or toxigenic microorganisms, the growth and toxin 147
production of clostridium botulinum, or in the case of raw 148
shell eggs, the growth of salmonella enteritidis. 149

(19) "Cottage food production operation" means a person 150
who, in the person's home, produces food items that are not 151
potentially hazardous foods, including bakery products, jams, 152
jellies, candy, fruit butter, and similar products specified in 153
rules adopted pursuant to section 3715.025 of the Revised Code. 154

(20) "Biological product" means, except as provided in 155
section 3715.011 of the Revised Code, a drug that is a 156
biological product, as defined on ~~the effective date of this~~ 157
~~amendment~~ March 21, 2017, in subsection (i) of section 351 of 158
the "Public Health Service Act," 42 U.S.C. 262(i). 159

(21) "Interchangeable biological product" means, except as provided in section 3715.011 of the Revised Code, both of the following:

(a) A biological product that, ~~on the effective date of this amendment~~ March 21, 2017, has been determined by the United States food and drug administration to meet the standards for interchangeability set forth in subsection (k) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), as amended, and has been licensed under that subsection;

(b) A biological product that, ~~prior to the effective date of this amendment~~ March 21, 2017, was determined by the United States food and drug administration to be therapeutically equivalent as set forth in its publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."

(22) "Kratom product" means food that contains any part of a leaf of the plant Mitragyna speciosa.

(B) For the purposes of sections 3715.52 to 3715.72 of the Revised Code:

(1) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequence which may result from the use of the article to which the labeling or advertisement relates under the conditions

of use prescribed in the labeling or advertisement thereof or 189
under such conditions of use as are customary or usual. 190

(2) The provisions regarding the selling of food, drugs, 191
devices, or cosmetics include the manufacture, production, 192
processing, packing, exposure, offer, possession, and holding of 193
any such article for sale; and the sale, dispensing, and giving 194
of any such article, and the supplying or applying of any such 195
articles in the conduct of any food, drug, or cosmetic 196
establishment. The provisions do not prohibit a licensed health 197
professional authorized to prescribe drugs from administering or 198
personally furnishing a drug or device to a patient. 199

(3) The representation of a drug, in its labeling or 200
advertisement, as an antiseptic is a representation that it is a 201
germicide, except in the case of a drug purporting to be, or 202
represented as, an antiseptic for inhibitory use as a wet 203
dressing, ointment, dusting powder, or other use that involves 204
prolonged contact with the body. 205

(4) Whenever jurisdiction is vested in the director of 206
agriculture or the state board of pharmacy, the jurisdiction of 207
the board shall be limited to the sale, offering for sale, 208
giving away, delivery, or dispensing in any manner of drugs at 209
the wholesale and retail levels or to the consumer and shall be 210
exclusive in the case of such sale, offering for sale, giving 211
away, delivery, or dispensing in any manner of drugs at the 212
wholesale and retail levels or to the consumer in any place 213
where prescriptions are dispensed or compounded. 214

(5) To assist in effectuating the provisions of those 215
sections, the director of agriculture or state board of pharmacy 216
may request assistance or data from any government or private 217
agency or individual. 218

Sec. 3715.026. (A) No food processing establishment 219
registered under section 3715.041 of the Revised Code shall 220
process, package, manufacture, hold or handle for distribution, 221
distribute, or sell a kratom product unless the establishment 222
has registered the kratom product with the director of 223
agriculture. To register a kratom product, a food processing 224
establishment shall apply to the director of agriculture in a 225
manner prescribed by the director. 226

(B) (1) No food processing establishment registered under 227
section 3715.041 of the Revised Code shall process, package, 228
manufacture, hold or handle for distribution, distribute, or 229
sell a kratom product that meets any of the following: 230

(a) Is mixed or packed with a substance that is not kratom 231
and that affects the quality or strength of the kratom product 232
to render the product injurious to a potential consumer; 233

(b) Contains a poisonous or otherwise deleterious 234
ingredient that is not kratom, including a controlled substance; 235

(c) Contains a level of 7-hydroxymitragynine in the 236
alkaloid fraction that is greater than one per cent of the 237
alkaloid composition of the kratom product; 238

(d) Contains a synthetic alkaloid, including synthetic 239
mitragynine, synthetic 7-hydroxymitragynine, or any other 240
synthetically derived compound of kratom; 241

(e) Does not include a product label on the kratom product 242
that states the amount of mitragynine and 7-hydroxymitragynine 243
contained in the product. 244

(2) A food processing establishment does not violate 245
division (B) (1) of this section if the establishment 246
demonstrates by a preponderance of the evidence that it relied 247

in good faith on the representation of another registered food 248
processing establishment that the kratom product meets the 249
requirements of division (B)(1) of this section. 250

(C) No food processing establishment registered under 251
section 3715.041 of the Revised Code shall distribute or sell a 252
kratom product without disclosing on the product's label the 253
factual basis on which the establishment represents the food as 254
a kratom product. 255

(D) No food processing establishment registered under 256
section 3715.041 of the Revised Code shall distribute or sell a 257
kratom product to an individual who is under eighteen years of 258
age. 259

(E) The director of agriculture shall adopt rules in 260
accordance with Chapter 119. of the Revised Code to implement 261
this section, including rules establishing all of the following: 262

(1) Application procedures and fees for registering a 263
kratom product; 264

(2) Civil penalties for any of the following: 265

(a) Failing to register a kratom product; 266

(b) Processing, packaging, manufacturing, or holding or 267
handling for distribution an unregistered kratom product; 268

(c) Failing to disclose on the kratom product's label the 269
factual basis on which the establishment represents the food as 270
a kratom product. 271

(3) Standards and procedures for appealing civil 272
penalties; 273

(4) Procedures for seizing and destroying a kratom product 274

<u>that does not meet the requirements of this section;</u>	275
<u>(5) Standards and procedures for kratom product testing;</u>	276
<u>(6) Standards for labeling of kratom products;</u>	277
<u>(7) Any other standards or procedures the director</u> <u>determines necessary to implement this section.</u>	278 279
<u>(F) Notwithstanding any provision of section 121.95 of the</u> <u>Revised Code to the contrary, a regulatory restriction contained</u> <u>in a rule adopted under this section is not subject to sections</u> <u>121.95 to 121.953 of the Revised Code.</u>	280 281 282 283
<u>(G) An individual may bring a civil action for damages</u> <u>resulting from a violation of divisions (A) to (D) of this</u> <u>section.</u>	284 285 286
Sec. 3715.99. (A) Whoever violates section 3715.13 or 3715.38 of the Revised Code is guilty of a minor misdemeanor.	287 288
(B) Whoever violates section 3715.22, 3715.25, or 3715.27 of the Revised Code is guilty of a misdemeanor of the fourth degree.	289 290 291
(C) Whoever violates section 3715.23 or 3715.34 of the Revised Code is guilty of a misdemeanor of the second degree.	292 293
(D) Whoever violates section 3715.52 or 3715.65 of the Revised Code is guilty of a misdemeanor of the fourth degree on a first offense; on each subsequent offense, the person is guilty of a misdemeanor of the second degree.	294 295 296 297
(E) Whoever violates section 3715.521 of the Revised Code is guilty of a minor misdemeanor. A violation of that section occurs on a daily basis, not according to the number of times per day that an expired drug, baby food, or infant formula is	298 299 300 301

sold, offered for sale, or delivered at retail or to the consumer. Each day of violation is a separate offense.

(F) Whoever recklessly violates division (B) or (D) of section 3715.026 of the Revised Code is guilty of a misdemeanor of the second degree.

Sec. 3717.01. As used in this chapter:

(A) "Ohio uniform food safety code" means the food safety and related standards adopted under section 3717.05 of the Revised Code.

(B) "Food" means any raw, cooked, or processed edible substance used or intended for use in whole or in part for human consumption. "Food" includes ice, water or any other beverage, food ingredients, and chewing gum.

(C) "Retail food establishment" means a premises or part of a premises where food is stored, processed, prepared, manufactured, or otherwise held or handled for retail sale. Except when expressly provided otherwise, "retail food establishment" includes a mobile retail food establishment, seasonal retail food establishment, and temporary retail food establishment.

As used in this division:

(1) "Retail" means the sale of food to a person who is the ultimate consumer.

(2) "Prepared" means any action that affects a food, including receiving and maintaining it at the temperature at which it was received.

(D) "Seasonal retail food establishment" means a retail food establishment, other than a mobile retail food

establishment, that is operated for not more than six months in 330
a licensing period. 331

(E) "Temporary retail food establishment" means a retail 332
food establishment that is operated at an event for not more 333
than five consecutive days, except when operated for more than 334
five consecutive days pursuant to division (E)(2) of section 335
3717.23 of the Revised Code. 336

(F) "Food service operation" means a place, location, 337
site, or separate area where food intended to be served in 338
individual portions is prepared or served for a charge or 339
required donation. As used in this division, "served" means a 340
response made to an order for one or more individual portions of 341
food in a form that is edible without washing, cooking, or 342
additional preparation and "prepared" means any action that 343
affects a food other than receiving or maintaining it at the 344
temperature at which it was received. 345

Except when expressly provided otherwise, "food service 346
operation" includes a catering food service operation, food 347
delivery sales operation, mobile food service operation, 348
seasonal food service operation, temporary food service 349
operation, and vending machine location. 350

(G) "Catering food service operation" means a food service 351
operation where food is prepared for serving at a function or 352
event held at an off-premises site, for a charge determined on a 353
per-function or per-event basis. 354

(H) "Food delivery sales operation" means a food service 355
operation from which individual portions of food are ordered by 356
a customer, prepared at another food service operation or a 357
retail food establishment, and delivered to the customer by a 358

person other than an employee of the food service operation or 359
retail food establishment that prepared the food. 360

(I) "Mobile food service operation" means a food service 361
operation that is operated from a movable vehicle, portable 362
structure, or watercraft and that routinely changes location, 363
except that if the operation remains at any one location for 364
more than forty consecutive days, the operation is no longer a 365
mobile food service operation. "Mobile food service operation" 366
includes a food service operation that does not remain at any 367
one location for more than forty consecutive days and serves, in 368
a manner consistent with division (F) of this section, only 369
frozen desserts; beverages, nuts, popcorn, candy, or similar 370
confections; bakery products identified in section 911.01 of the 371
Revised Code; or any combination of those items. 372

(J) "Seasonal food service operation" means a food service 373
operation, other than a mobile food service operation, that is 374
operated for not more than six months in a licensing period. 375

(K) "Temporary food service operation" means a food 376
service operation that is operated at an event for not more than 377
five consecutive days, except when operated for more than five 378
consecutive days pursuant to division (E) (2) of section 3717.43 379
of the Revised Code. 380

(L) "Vending machine location" means an area or room where 381
one or more vending machines are installed and operated, except 382
that if the machines within an area are separated by more than 383
one hundred fifty feet, each area separated by that distance 384
constitutes a separate vending machine location. As used in this 385
division, "vending machine" means a self-service device that 386
automatically dispenses on the insertion of currency, tokens, or 387
similar means a predetermined unit serving of food, either in 388

bulk or in package, without having to be replenished after each use.	389 390
(M) "Board of health" means a board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code.	391 392 393
(N) "Government entity" means this state, a political subdivision of this state, another state, or a political subdivision or other local government body of another state.	394 395 396
(O) "Licensor" means one of the following:	397
(1) A board of health approved under section 3717.11 of the Revised Code;	398 399
(2) The director of agriculture acting pursuant to section 3717.11 of the Revised Code with respect to the licensing of retail food establishments;	400 401 402
(3) The director of health acting pursuant to section 3717.11 of the Revised Code with respect to the licensing of food service operations.	403 404 405
(P) "Licensing period" means the first day of March to the last day of February of the next succeeding year.	406 407
(Q) "Mobile retail food establishment" means a retail food establishment that is operated from a movable vehicle or other portable structure, and that routinely changes location, except that if the establishment operates from any one location for more than forty consecutive days, the establishment is no longer a mobile retail food establishment.	408 409 410 411 412 413
(R) "Unprocessed," when used with respect to fruits and vegetables, means that the fruits and vegetables are not processed beyond merely rough trimming and rinsing.	414 415 416

(S) "Cottage food production operation" has the same 417
meaning as in division (A) (19) of section 3715.01 of the Revised 418
Code. 419

(T) "Kratom product" means food that contains any part of 420
a leaf of the plant Mitragyna speciosa. 421

Sec. 3717.34. (A) No retail food establishment license 422
holder shall store, process, prepare, manufacture, hold or 423
handle for retail sale, or sell a kratom product unless the 424
establishment has registered the kratom product with the 425
director of agriculture. To register a kratom product, a retail 426
food establishment license holder shall apply to the director of 427
agriculture or director of health in a manner prescribed by the 428
director. 429

(B) (1) No retail food establishment license holder shall 430
store, process, prepare, manufacture, hold or handle for retail 431
sale, or sell a kratom product that meets any of the following: 432

(a) Is mixed or packed with a substance that is not kratom 433
and that affects the quality or strength of the kratom product 434
to render the product injurious to a potential consumer; 435

(b) Contains a poisonous or otherwise deleterious 436
ingredient that is not kratom, including a controlled substance; 437

(c) Contains a level of 7-hydroxymitragynine in the 438
alkaloid fraction that is greater than one per cent of the 439
alkaloid composition of the kratom product; 440

(d) Contains a synthetic alkaloid, including synthetic 441
mitragynine, synthetic 7-hydroxymitragynine, or any other 442
synthetically derived compound of kratom; 443

(e) Does not include a product label on the kratom product 444

that states the amount of mitragynine and 7-hydroxymitragynine 445
contained in the product. 446

(2) A retail food establishment license holder does not 447
violate division (B)(1) of this section if the holder 448
demonstrates by a preponderance of the evidence that the holder 449
relied in good faith on the representation of another license 450
holder or a food processing establishment registered under 451
section 3715.041 of the Revised Code that the kratom product 452
meets the requirements of division (B)(1) of this section. 453

(C) No retail food establishment license holder shall sell 454
a kratom product without disclosing on the product's label the 455
factual basis on which the holder represents the food as a 456
kratom product. 457

(D) No retail food establishment license holder shall sell 458
a kratom product to an individual who is under eighteen years of 459
age. 460

(E) The director of agriculture and director of health 461
shall adopt rules in accordance with Chapter 119. of the Revised 462
Code to implement this section, including rules establishing all 463
of the following: 464

(1) Application procedures and fees for registering a 465
kratom product; 466

(2) Civil penalties for any of the following: 467

(a) Failing to register a kratom product; 468

(b) Selling an unregistered kratom product; 469

(c) Failing to disclose on the kratom product's label the 470
factual basis on which the holder represents the food as a 471
kratom product. 472

<u>(3) Standards and procedures for appealing civil penalties;</u>	473 474
<u>(4) Procedures for seizing and destroying a kratom product that does not meet the requirements of this section;</u>	475 476
<u>(5) Standards and procedures for kratom product testing;</u>	477
<u>(6) Standards for labeling of kratom products;</u>	478
<u>(7) Any other standards or procedures the director determines necessary to implement this section.</u>	479 480
<u>(F) Notwithstanding any provision of section 121.95 of the Revised Code to the contrary, a regulatory restriction contained in a rule adopted under this section is not subject to sections 121.95 to 121.953 of the Revised Code.</u>	481 482 483 484
<u>(G) An individual may bring a civil action for damages resulting from a violation of divisions (A) to (D) of this section.</u>	485 486 487
Sec. 3717.99. Whoever violates section 3717.21 or 3717.41 of the Revised Code is guilty of a misdemeanor of the third degree on a first offense; for a second offense or subsequent offense, such person is guilty of a misdemeanor of the second degree. Each day the violation continues is a separate offense.	488 489 490 491 492
<u>Whoever recklessly violates division (B) or (D) of section 3717.34 of the Revised Code is guilty of a misdemeanor of the second degree.</u>	493 494 495
Section 2. That existing sections 3715.01, 3715.99, 3717.01, and 3717.99 of the Revised Code are hereby repealed.	496 497
Section 3. This act shall be known as the "Kratom Consumer Protection Act."	498 499