

As Introduced

**133rd General Assembly
Regular Session
2019-2020**

H. B. No. 318

Representative Scherer

A BILL

To amend sections 3715.01, 3715.99, 3717.01, and 1
3719.99 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
19
20

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; 21
22
23

(d) Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories. 24
25
26

(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
28
29
30
31
32
33

(a) Recognized in the United States pharmacopoeia and national formulary, or any supplement to them; 34
35

(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
37
38

(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
40
41
42
43
44

(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 botulinium, 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 <u>March 21, 2017</u> , 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

<u>Sec. 3715.026. (A) No food processing establishment</u>	219
<u>registered under section 3715.041 of the Revised Code shall</u>	220
<u>process, package, manufacture, hold or handle for distribution,</u>	221
<u>distribute, or sell a kratom product unless the establishment</u>	222
<u>has registered the kratom product with the director of</u>	223
<u>agriculture. To register a kratom product, a food processing</u>	224
<u>establishment shall apply to the director of agriculture in a</u>	225
<u>manner prescribed by the director.</u>	226
<u>(B) (1) No food processing establishment registered under</u>	227
<u>section 3715.041 of the Revised Code shall process, package,</u>	228
<u>manufacture, hold or handle for distribution, distribute, or</u>	229
<u>sell a kratom product that meets any of the following:</u>	230
<u>(a) Is mixed or packed with a substance that is not kratom</u>	231
<u>and that affects the quality or strength of the kratom product</u>	232
<u>to render the product injurious to a potential consumer;</u>	233
<u>(b) Contains a poisonous or otherwise deleterious</u>	234
<u>ingredient that is not kratom, including a controlled substance;</u>	235
<u>(c) Contains a level of 7-hydroxymitragynine in the</u>	236
<u>alkaloid fraction that is greater than two per cent of the</u>	237
<u>alkaloid composition of the kratom product;</u>	238
<u>(d) Contains a synthetic alkaloid, including synthetic</u>	239
<u>mitragynine, synthetic 7-hydroxymitragynine, or any other</u>	240
<u>synthetically derived compound of kratom;</u>	241
<u>(e) Does not include a product label on the kratom product</u>	242
<u>that states the amount of mitragynine and 7-hydroxymitragynine</u>	243
<u>contained in the product.</u>	244
<u>(2) A food processing establishment does not violate</u>	245
<u>division (B) (1) of this section if the establishment</u>	246
<u>demonstrates by a preponderance of the evidence that it relied</u>	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 CCode 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 to 260
implement this section, including rules establishing all of the 261
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>The rules shall be adopted in accordance with Chapter 119.</u> <u>of the Revised Code.</u>	280 281
<u>(F) 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>	282 283 284
Sec. 3715.99. (A) Whoever violates sections 3715.13 to 3715.19, or 3715.38 of the Revised Code is guilty of a minor misdemeanor.	285 286 287
(B) Whoever violates section 3715.22, 3715.25, 3715.27, or 3715.34 of the Revised Code is guilty of a misdemeanor of the fourth degree.	288 289 290
(C) Whoever violates section 3715.23 or 3715.36 of the Revised Code is guilty of a misdemeanor of the second degree.	291 292
(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.	293 294 295 296
(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 sold, offered for sale, or delivered at retail or to the	297 298 299 300 301

consumer. Each day of violation is a separate offense.	302
<u>(F) Whoever violates division (B) or (D) of section</u>	303
<u>3715.026 of the Revised Code is guilty of a misdemeanor of the</u>	304
<u>second degree.</u>	305
Sec. 3717.01. As used in this chapter:	306
(A) "Ohio uniform food safety code" means the food safety	307
and related standards adopted under section 3717.05 of the	308
Revised Code.	309
(B) "Food" means any raw, cooked, or processed edible	310
substance used or intended for use in whole or in part for human	311
consumption. "Food" includes ice, water or any other beverage,	312
food ingredients, and chewing gum.	313
(C) "Retail food establishment" means a premises or part	314
of a premises where food is stored, processed, prepared,	315
manufactured, or otherwise held or handled for retail sale.	316
Except when expressly provided otherwise, "retail food	317
establishment" includes a mobile retail food establishment,	318
seasonal retail food establishment, and temporary retail food	319
establishment.	320
As used in this division:	321
(1) "Retail" means the sale of food to a person who is the	322
ultimate consumer.	323
(2) "Prepared" means any action that affects a food,	324
including receiving and maintaining it at the temperature at	325
which it was received.	326
(D) "Seasonal retail food establishment" means a retail	327
food establishment, other than a mobile retail food	328
establishment, that is operated for not more than six months in	329

a licensing period. 330

(E) "Temporary retail food establishment" means a retail 331
food establishment that is operated at an event for not more 332
than five consecutive days, except when operated for more than 333
five consecutive days pursuant to division (E)(2) of section 334
3717.23 of the Revised Code. 335

(F) "Food service operation" means a place, location, 336
site, or separate area where food intended to be served in 337
individual portions is prepared or served for a charge or 338
required donation. As used in this division, "served" means a 339
response made to an order for one or more individual portions of 340
food in a form that is edible without washing, cooking, or 341
additional preparation and "prepared" means any action that 342
affects a food other than receiving or maintaining it at the 343
temperature at which it was received. 344

Except when expressly provided otherwise, "food service 345
operation" includes a catering food service operation, food 346
delivery sales operation, mobile food service operation, 347
seasonal food service operation, temporary food service 348
operation, and vending machine location. 349

(G) "Catering food service operation" means a food service 350
operation where food is prepared for serving at a function or 351
event held at an off-premises site, for a charge determined on a 352
per-function or per-event basis. 353

(H) "Food delivery sales operation" means a food service 354
operation from which individual portions of food are ordered by 355
a customer, prepared at another food service operation or a 356
retail food establishment, and delivered to the customer by a 357
person other than an employee of the food service operation or 358

retail food establishment that prepared the food. 359

(I) "Mobile food service operation" means a food service 360
operation that is operated from a movable vehicle, portable 361
structure, or watercraft and that routinely changes location, 362
except that if the operation remains at any one location for 363
more than forty consecutive days, the operation is no longer a 364
mobile food service operation. "Mobile food service operation" 365
includes a food service operation that does not remain at any 366
one location for more than forty consecutive days and serves, in 367
a manner consistent with division (F) of this section, only 368
frozen desserts; beverages, nuts, popcorn, candy, or similar 369
confections; bakery products identified in section 911.01 of the 370
Revised Code; or any combination of those items. 371

(J) "Seasonal food service operation" means a food service 372
operation, other than a mobile food service operation, that is 373
operated for not more than six months in a licensing period. 374

(K) "Temporary food service operation" means a food 375
service operation that is operated at an event for not more than 376
five consecutive days, except when operated for more than five 377
consecutive days pursuant to division (E) (2) of section 3717.43 378
of the Revised Code. 379

(L) "Vending machine location" means an area or room where 380
one or more vending machines are installed and operated, except 381
that if the machines within an area are separated by more than 382
one hundred fifty feet, each area separated by that distance 383
constitutes a separate vending machine location. As used in this 384
division, "vending machine" means a self-service device that 385
automatically dispenses on the insertion of currency, tokens, or 386
similar means a predetermined unit serving of food, either in 387
bulk or in package, without having to be replenished after each 388

use.	389
(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.	390 391 392
(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.	393 394 395
(O) "Licensor" means one of the following:	396
(1) A board of health approved under section 3717.11 of the Revised Code;	397 398
(2) The director of agriculture acting pursuant to section 3717.11 of the Revised Code with respect to the licensing of retail food establishments;	399 400 401
(3) The director of health acting pursuant to section 3717.11 of the Revised Code with respect to the licensing of food service operations.	402 403 404
(P) "Licensing period" means the first day of March to the last day of February of the next succeeding year.	405 406
(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.	407 408 409 410 411 412
(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.	413 414 415

(S) "Cottage food production operation" has the same 416
meaning as in division (A) (19) of section 3715.01 of the Revised 417
Code. 418

(T) "Kratom product" means food that contains any part of 419
a leaf of the plant Mitragyna speciosa. 420

Sec. 3717.34. (A) No retail food establishment license 421
holder shall store, process, prepare, manufacture, hold or 422
handle for retail sale, or sell a kratom product unless the 423
establishment has registered the kratom product with the 424
director of agriculture. To register a kratom product, a retail 425
food establishment license holder shall apply to the director of 426
agriculture or director of health in a manner prescribed by the 427
director. 428

(B) (1) No retail food establishment license holder shall 429
store, process, prepare, manufacture, hold or handle for retail 430
sale, or sell a kratom product that meets any of the following: 431

(a) Is mixed or packed with a substance that is not kratom 432
and that affects the quality or strength of the kratom product 433
to render the product injurious to a potential consumer; 434

(b) Contains a poisonous or otherwise deleterious 435
ingredient that is not kratom, including a controlled substance; 436

(c) Contains a level of 7-hydroxymitragynine in the 437
alkaloid fraction that is greater than two per cent of the 438
alkaloid composition of the kratom product; 439

(d) Contains a synthetic alkaloid, including synthetic 440
mitragynine, synthetic 7-hydroxymitragynine, or any other 441
synthetically derived compound of kratom; 442

(e) Does not include a product label on the kratom product 443

that states the amount of mitragynine and 7-hydroxymitragynine 444
contained in the product. 445

(2) A retail food establishment license holder does not 446
violate division (B)(1) of this section if the holder 447
demonstrates by a preponderance of the evidence that the holder 448
relied in good faith on the representation of another license 449
holder or a food processing establishment registered under 450
section 3715.041 of the Revised Code that the kratom product 451
meets the requirements of division (B)(1) of this section. 452

(C) No retail food establishment license holder shall sell 453
a kratom product without disclosing on the product's label the 454
factual basis on which the holder represents the food as a 455
kratom product. 456

(D) No retail food establishment license holder shall sell 457
a kratom product to an individual who is under eighteen years of 458
age. 459

(E) The director of agriculture and director of health 460
shall adopt rules to implement this section, including rules 461
establishing all of the following: 462

(1) Application procedures and fees for registering a 463
kratom product; 464

(2) Civil penalties for any of the following: 465

(a) Failing to register a kratom product; 466

(b) Selling an unregistered kratom product; 467

(c) Failing to disclose on the kratom product's label the 468
factual basis on which the holder represents the food as a 469
kratom product. 470

<u>(3) Standards and procedures for appealing civil penalties;</u>	471 472
<u>(4) Procedures for seizing and destroying a kratom product that does not meet the requirements of this section;</u>	473 474
<u>(5) Standards and procedures for kratom product testing;</u>	475
<u>(6) Standards for labeling of kratom products;</u>	476
<u>(7) Any other standards or procedures the director determines necessary to implement this section.</u>	477 478
<u>The rules shall be adopted in accordance with Chapter 119. of the Revised Code.</u>	479 480
<u>(F) An individual may bring a civil action for damages resulting from a violation of divisions (A) to (D) of this section.</u>	481 482 483
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.	484 485 486 487 488
<u>Whoever violates division (B) or (D) of section 3717.34 of the Revised Code is guilty of a misdemeanor of the second degree.</u>	489 490 491
Section 2. That existing sections 3715.01, 3715.99, 3717.01, and 3717.99 of the Revised Code are hereby repealed.	492 493
Section 3. This act shall be known as the "Kratom Consumer Protection Act."	494 495