

As Introduced

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Representatives Odioso, Lorenz

Cosponsor: Representative Somani

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, 18
mitigation, treatment, or prevention of disease in humans or 19
animals; 20

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

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

(4) "Device," except when used in division (B)(1) of this 27
section and in division (A)(10) of section 3715.52, division (F) 28
of section 3715.60, division (A)(5) of section 3715.64, and 29
division (C) of section 3715.67 of the Revised Code, means any 30
instrument, apparatus, implement, machine, contrivance, implant, 31
in vitro reagent, or other similar or related article, including 32
any component, part, or accessory, that is any of the following: 33

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

(b) Intended for use in the diagnosis of disease or other 36
conditions, or in the cure, mitigation, treatment, or prevention 37
of disease in humans or animals; 38

(c) Intended to affect the structure or any function of 39
the body of humans or animals, and that does not achieve any of 40
its principal intended purposes through chemical action within 41
or on the body of humans or animals and is not dependent upon 42
being metabolized for the achievement of any of its principal 43
intended purposes. 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 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" means the plant Mitragyna speciosa and any
part of that plant.

(23) "Kratom product" means a finished article containing
either of the following:

(a) Any part of a leaf of the plant Mitragyna speciosa in
fresh, dehydrated, or dried form;

(b) A kratom extract that is manufactured using United
States food and drug administration approved food grade
solvents.

(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 188
into account, among other things, not only representations made 189
or suggested by statement, word, design, device, sound, or in 190
any combination thereof, but also the extent to which the 191
labeling or advertisement fails to reveal facts material in the 192
light of such representations or material with respect to 193
consequence which may result from the use of the article to 194
which the labeling or advertisement relates under the conditions 195
of use prescribed in the labeling or advertisement thereof or 196
under such conditions of use as are customary or usual. 197

(2) The provisions regarding the selling of food, drugs, 198
devices, or cosmetics include the manufacture, production, 199
processing, packing, exposure, offer, possession, and holding of 200
any such article for sale; and the sale, dispensing, and giving 201
of any such article, and the supplying or applying of any such 202
articles in the conduct of any food, drug, or cosmetic 203
establishment. The provisions do not prohibit a licensed health 204
professional authorized to prescribe drugs from administering or 205
personally furnishing a drug or device to a patient. 206

(3) The representation of a drug, in its labeling or 207
advertisement, as an antiseptic is a representation that it is a 208
germicide, except in the case of a drug purporting to be, or 209
represented as, an antiseptic for inhibitory use as a wet 210
dressing, ointment, dusting powder, or other use that involves 211
prolonged contact with the body. 212

(4) Whenever jurisdiction is vested in the director of 213
agriculture or the state board of pharmacy, the jurisdiction of 214
the board shall be limited to the sale, offering for sale, 215
giving away, delivery, or dispensing in any manner of drugs at 216
the wholesale and retail levels or to the consumer and shall be 217

exclusive in the case of such sale, offering for sale, giving 218
away, delivery, or dispensing in any manner of drugs at the 219
wholesale and retail levels or to the consumer in any place 220
where prescriptions are dispensed or compounded. 221

(5) To assist in effectuating the provisions of those 222
sections, the director of agriculture or state board of pharmacy 223
may request assistance or data from any government or private 224
agency or individual. 225

Sec. 3715.026. (A) As used in this section: 226

(1) "Food processing establishment" has the same meaning 227
as in section 3715.021 of the Revised Code and includes any 228
premises or part of a premises where kratom is processed, 229
packaged, manufactured, or otherwise held or handled for 230
distribution to another location or for sale at wholesale. 231

(2) "Synthesized material" means an alkaloid, metabolite 232
of an alkaloid, or alkaloid derivative that has been created by 233
chemical synthesis or biosynthetic means, including 234
fermentation, recombinant techniques, yeast derived, enzymatic 235
techniques, and oxidation. "Synthesized material" does not 236
include an alkaloid, metabolite of an alkaloid, or alkaloid 237
derivative created by traditional food preparation techniques. 238

(3) "Semi-synthetic alkaloid" means a substance derived 239
from an alkaloid naturally occurring in kratom that has been 240
chemically altered through chemical reactions, including 241
oxidation, reduction, acetylation, or other processes to change 242
the structure or pharmacological activity of the naturally 243
occurring kratom alkaloid. "Semi-synthetic alkaloid" includes 244
the synthesis of 7-hydroxymitragynine when produced by chemical 245
alteration of mitragynine. 246

(4) "Synthetic kratom-like compound" means a synthesized 247
material that is not found naturally in the Mitragyna speciosa 248
plant and is created entirely through laboratory synthesis to 249
mimic the pharmacological effects of kratom alkaloids or 250
constituent. 251

(B) No food processing establishment registered under 252
section 3715.041 of the Revised Code shall process, package, 253
manufacture, hold or handle for distribution, distribute, or 254
sell a kratom product unless the establishment has registered 255
the kratom product with the director of agriculture. To register 256
a kratom product, a food processing establishment shall apply to 257
the director of agriculture in a manner prescribed by the 258
director. 259

(C) (1) No food processing establishment registered under 260
section 3715.041 of the Revised Code shall process, package, 261
manufacture, hold or handle for distribution, distribute, or 262
sell a kratom product that meets any of the following: 263

(a) Contains a controlled substance or a residual solvent 264
higher than is allowed in the United States Pharmacopeia 265
(U.S.P.) general chapter 467; 266

(b) Contains a level of naturally occurring 7- 267
hydroxymitragynine in the alkaloid fraction that is greater than 268
two per cent of the alkaloid composition of the kratom product 269
and contains a level of 7-hydroxymitragynine that is greater 270
than one milligram per serving in its final product form, as 271
documented by a certificate of analysis on the finished product 272
prior to distribution; 273

(c) Contains a synthetic kratom-like compound or semi- 274
synthetic alkaloid where mitragynine is not the majority of the 275

<u>alkaloid in the product;</u>	276
<u>(d) Does not include a product label on the kratom product</u>	277
<u>that states the amount of mitragynine and 7-hydroxymitragynine</u>	278
<u>contained in the product.</u>	279
<u>(2) A food processing establishment does not violate</u>	280
<u>division (C) (1) of this section if the establishment</u>	281
<u>demonstrates by a preponderance of the evidence that it relied</u>	282
<u>in good faith on the representation of another registered food</u>	283
<u>processing establishment that the kratom product meets the</u>	284
<u>requirements of division (C) (1) of this section.</u>	285
<u>(D) No food processing establishment registered under</u>	286
<u>section 3715.041 of the Revised Code shall distribute or sell a</u>	287
<u>kratom product without disclosing to the director of agriculture</u>	288
<u>at the time the product is registered the factual basis on which</u>	289
<u>the establishment represents the food as a kratom product.</u>	290
<u>(E) No food processing establishment registered under</u>	291
<u>section 3715.041 of the Revised Code shall distribute or sell a</u>	292
<u>kratom product to an individual who is under eighteen years of</u>	293
<u>age.</u>	294
<u>(F) The director of agriculture shall adopt rules in</u>	295
<u>accordance with Chapter 119. of the Revised Code to implement</u>	296
<u>this section, including rules establishing all of the following:</u>	297
<u>(1) Application procedures and a fee for registering a</u>	298
<u>kratom product. The registration fee established under this</u>	299
<u>section shall be based on the square footage of the food</u>	300
<u>processing establishment and shall not exceed the registration</u>	301
<u>fee for the establishment specified in rule 901:3-21-01 of the</u>	302
<u>Administrative Code.</u>	303
<u>(2) Civil penalties for any of the following:</u>	304

<u>(a) Failing to register a kratom product;</u>	305
<u>(b) Processing, packaging, manufacturing, or holding or</u>	306
<u>handling for distribution an unregistered kratom product;</u>	307
<u>(c) Failing to disclose on the kratom product's label the</u>	308
<u>factual basis on which the establishment represents the food as</u>	309
<u>a kratom product.</u>	310
<u>(3) Standards and procedures for appealing civil</u>	311
<u>penalties;</u>	312
<u>(4) Procedures for seizing and destroying a kratom product</u>	313
<u>that does not meet the requirements of this section;</u>	314
<u>(5) Standards and procedures for kratom product testing;</u>	315
<u>(6) Standards for labeling of kratom products;</u>	316
<u>(7) Any other standards or procedures the director</u>	317
<u>determines necessary to implement this section.</u>	318
<u>(G) Notwithstanding any provision of section 121.95 of the</u>	319
<u>Revised Code to the contrary, a regulatory restriction contained</u>	320
<u>in a rule adopted under this section is not subject to sections</u>	321
<u>121.95 to 121.953 of the Revised Code.</u>	322
<u>(H) An individual may bring a civil action for damages</u>	323
<u>resulting from a violation of divisions (B) to (E) of this</u>	324
<u>section.</u>	325
Sec. 3715.99. (A) Whoever violates section 3715.13 or	326
3715.38 of the Revised Code is guilty of a minor misdemeanor.	327
(B) Whoever violates section 3715.22, 3715.25, or 3715.27	328
of the Revised Code is guilty of a misdemeanor of the fourth	329
degree.	330
(C) Whoever violates section 3715.23 or 3715.34 of the	331

Revised Code is guilty of a misdemeanor of the second degree. 332

(D) Whoever violates section 3715.52 or 3715.65 of the 333
Revised Code is guilty of a misdemeanor of the fourth degree on 334
a first offense; on each subsequent offense, the person is 335
guilty of a misdemeanor of the second degree. 336

(E) Whoever violates section 3715.521 of the Revised Code 337
is guilty of a minor misdemeanor. A violation of that section 338
occurs on a daily basis, not according to the number of times 339
per day that an expired drug, baby food, or infant formula is 340
sold, offered for sale, or delivered at retail or to the 341
consumer. Each day of violation is a separate offense. 342

(F) Whoever recklessly violates division (C) or (E) of 343
section 3715.026 of the Revised Code is guilty of a misdemeanor 344
of the second degree. 345

Sec. 3717.01. As used in this chapter: 346

(A) "Ohio uniform food safety code" means the food safety 347
and related standards adopted under section 3717.05 of the 348
Revised Code. 349

(B) "Food" means any raw, cooked, or processed edible 350
substance used or intended for use in whole or in part for human 351
consumption. "Food" includes ice, water or any other beverage, 352
food ingredients, and chewing gum. 353

(C) "Retail food establishment" means a premises or part 354
of a premises where food is stored, processed, prepared, 355
manufactured, or otherwise held or handled for retail sale. 356
Except when expressly provided otherwise, "retail food 357
establishment" includes a mobile retail food establishment, 358
seasonal retail food establishment, and temporary retail food 359
establishment. 360

As used in this division: 361

(1) "Retail" means the sale of food to a person who is the 362
ultimate consumer. 363

(2) "Prepared" means any action that affects a food, 364
including receiving and maintaining it at the temperature at 365
which it was received. 366

(D) "Seasonal retail food establishment" means a retail 367
food establishment, other than a mobile retail food 368
establishment, that is operated for not more than six months in 369
a licensing period. 370

(E) "Temporary retail food establishment" means a retail 371
food establishment that is operated at an event for not more 372
than five consecutive days, except when operated for more than 373
five consecutive days pursuant to division (E)(2) of section 374
3717.23 of the Revised Code. 375

(F) "Food service operation" means a place, location, 376
site, or separate area where food intended to be served in 377
individual portions is prepared or served for a charge or 378
required donation. As used in this division, "served" means a 379
response made to an order for one or more individual portions of 380
food in a form that is edible without washing, cooking, or 381
additional preparation and "prepared" means any action that 382
affects a food other than receiving or maintaining it at the 383
temperature at which it was received. 384

Except when expressly provided otherwise, "food service 385
operation" includes a catering food service operation, food 386
delivery sales operation, mobile food service operation, 387
seasonal food service operation, temporary food service 388
operation, and vending machine location. 389

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

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

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

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

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

(L) "Vending machine location" means an area or room where 420
one or more vending machines are installed and operated, except 421
that if the machines within an area are separated by more than 422
one hundred fifty feet, each area separated by that distance 423
constitutes a separate vending machine location. As used in this 424
division, "vending machine" means a self-service device that 425
automatically dispenses on the insertion of currency, tokens, or 426
similar means a predetermined unit serving of food, either in 427
bulk or in package, without having to be replenished after each 428
use. 429

(M) "Board of health" means a board of health of a city or 430
general health district or the authority having the duties of a 431
board of health under section 3709.05 of the Revised Code. 432

(N) "Government entity" means this state, a political 433
subdivision of this state, another state, or a political 434
subdivision or other local government body of another state. 435

(O) "Licensor" means one of the following: 436

(1) A board of health approved under section 3717.11 of 437
the Revised Code; 438

(2) The director of agriculture acting pursuant to section 439
3717.11 of the Revised Code with respect to the licensing of 440
retail food establishments; 441

(3) The director of health acting pursuant to section 442
3717.11 of the Revised Code with respect to the licensing of 443
food service operations. 444

(P) "Licensing period" means the first day of March to the 445
last day of February of the next succeeding year. 446

(Q) "Mobile retail food establishment" means a retail food 447

establishment that is operated from a movable vehicle or other 448
portable structure, and that routinely changes location, except 449
that if the establishment operates from any one location for 450
more than forty consecutive days, the establishment is no longer 451
a mobile retail food establishment. 452

(R) "Unprocessed," when used with respect to fruits and 453
vegetables, means that the fruits and vegetables are not 454
processed beyond merely rough trimming and rinsing. 455

(S) "Cottage food production operation" has the same 456
meaning as in division (A) (19) of section 3715.01 of the Revised 457
Code. 458

(T) "Kratom" and "kratom product" have the same meanings 459
as in section 3715.01 of the Revised Code. 460

Sec. 3717.34. (A) As used in this section: 461

(1) "Synthesized material" means an alkaloid, metabolite 462
of an alkaloid, or alkaloid derivative that has been created by 463
chemical synthesis or biosynthetic means, including 464
fermentation, recombinant techniques, yeast derived, enzymatic 465
techniques, and oxidation. "Synthesized material" does not 466
include an alkaloid, metabolite of an alkaloid, or alkaloid 467
derivative created by traditional food preparation techniques. 468

(2) "Semi-synthetic alkaloid" means a substance derived 469
from an alkaloid naturally occurring in kratom that has been 470
chemically altered through chemical reactions, including 471
oxidation, reduction, acetylation, or other processes to change 472
the structure or pharmacological activity of the naturally 473
occurring kratom alkaloid. "Semi-synthetic alkaloid" includes 474
the synthesis of 7-hydroxymitragynine when produced by chemical 475
alteration of mitragynine. 476

(3) "Synthetic kratom-like compound" means a synthesized 477
material that is not found naturally in the Mitragyna speciosa 478
plant and is created entirely through laboratory synthesis to 479
mimic the pharmacological effects of kratom alkaloids. 480

(B) No retail food establishment license holder shall 481
store, process, prepare, manufacture, hold or handle for retail 482
sale, or sell a kratom product unless the establishment has 483
registered the kratom product with the director of agriculture. 484
To register a kratom product, a retail food establishment 485
license holder shall apply to the director of agriculture or 486
director of health in a manner prescribed by the director. 487

(C) (1) No retail food establishment license holder shall 488
store, process, prepare, manufacture, hold or handle for retail 489
sale, or sell a kratom product that meets any of the following: 490

(a) Contains a controlled substance or a residual solvent 491
higher than is allowed in the United States Pharmacopeia 492
(U.S.P.) general chapter 467; 493

(b) Contains a level of naturally occurring 7- 494
hydroxymitragynine in the alkaloid fraction that is greater than 495
two per cent of the alkaloid composition of the kratom product 496
and contains a level of 7-hydroxymitragynine that is greater 497
than one milligram per serving in its final product form, as 498
documented by a certificate of analysis on the finished product 499
prior to distribution; 500

(c) Contains a synthetic kratom-like compound or semi- 501
synthetic alkaloid where mitragynine is not the majority of the 502
alkaloid in the product; 503

(d) Does not include a product label on the kratom product 504
that states the amount of mitragynine and 7-hydroxymitragynine 505

contained in the product. 506

(2) A retail food establishment license holder does not 507
violate division (C) (1) of this section if the holder 508
demonstrates by a preponderance of the evidence that the holder 509
relied in good faith on the representation of another license 510
holder or a food processing establishment registered under 511
section 3715.041 of the Revised Code that the kratom product 512
meets the requirements of division (C) (1) of this section. 513

(D) No retail food establishment license holder shall sell 514
a kratom product without disclosing to the director of 515
agriculture at the time the product is registered the factual 516
basis on which the holder represents the food as a kratom 517
product. 518

(E) No retail food establishment license holder shall sell 519
a kratom product to an individual who is under eighteen years of 520
age. 521

(F) The director of agriculture and director of health 522
shall adopt rules in accordance with Chapter 119. of the Revised 523
Code to implement this section, including rules establishing all 524
of the following: 525

(1) Application procedures and a fee for registering a 526
kratom product. The registration fee for a retail food 527
establishment established under this section shall be based on 528
the square footage of the retail food establishment and shall 529
not exceed the registration fee for a food processing 530
establishment with equivalent square footage specified in rule 531
901:3-21-01 of the Administrative Code. 532

(2) Civil penalties for any of the following: 533

(a) Failing to register a kratom product; 534

<u>(b) Selling an unregistered kratom product;</u>	535
<u>(c) Failing to disclose on the kratom product's label the</u>	536
<u>factual basis on which the holder represents the food as a</u>	537
<u>kratom product.</u>	538
<u>(3) Standards and procedures for appealing civil</u>	539
<u>penalties;</u>	540
<u>(4) Procedures for seizing and destroying a kratom product</u>	541
<u>that does not meet the requirements of this section;</u>	542
<u>(5) Standards and procedures for kratom product testing;</u>	543
<u>(6) Standards for labeling of kratom products;</u>	544
<u>(7) Any other standards or procedures the director</u>	545
<u>determines necessary to implement this section.</u>	546
<u>(G) Notwithstanding any provision of section 121.95 of the</u>	547
<u>Revised Code to the contrary, a regulatory restriction contained</u>	548
<u>in a rule adopted under this section is not subject to sections</u>	549
<u>121.95 to 121.953 of the Revised Code.</u>	550
<u>(H) An individual may bring a civil action for damages</u>	551
<u>resulting from a violation of divisions (A) to (D) of this</u>	552
<u>section.</u>	553
Sec. 3717.99. <u>Whoever violates section 3717.21 or 3717.41</u>	554
<u>of the Revised Code is guilty of a misdemeanor of the third</u>	555
<u>degree on a first offense; for a second offense or subsequent</u>	556
<u>offense, such person is guilty of a misdemeanor of the second</u>	557
<u>degree. Each day the violation continues is a separate offense.</u>	558
<u>Whoever recklessly violates division (C) or (E) of section</u>	559
<u>3717.34 of the Revised Code is guilty of a misdemeanor of the</u>	560
<u>second degree.</u>	561

Section 2. That existing sections 3715.01, 3715.99,	562
3717.01, and 3717.99 of the Revised Code are hereby repealed.	563