

**As Introduced**

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

**H. B. No. 318**

**Representative Scherer**

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**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  
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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 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~~ 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 two 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 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
<b>Sec. 3715.99.</b> (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

(F) Whoever violates division (B) or (D) of section 303  
3715.026 of the Revised Code is guilty of a misdemeanor of the 304  
second degree. 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
<b>Sec. 3717.99.</b> 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
<b>Section 2.</b> That existing sections 3715.01, 3715.99, 3717.01, and 3717.99 of the Revised Code are hereby repealed.	492 493
<b>Section 3.</b> This act shall be known as the "Kratom Consumer Protection Act."	494 495