

As Introduced

135th General Assembly

Regular Session

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H. B. No. 495

Representatives Carruthers, Sweeney

**Cosponsors: Representatives Grim, Brennan, Brent, Robb Blasdel, Russo,
Dell'Aquila**

A BILL

To amend sections 3715.01, 3715.025, 3715.99, and 1
3717.01 and to enact section 3715.522 of the 2
Revised Code to prohibit the sale of cosmetics 3
tested on animals except under certain specified 4
circumstances. 5

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

Section 1. That sections 3715.01, 3715.025, 3715.99, and 6
3717.01 be amended and section 3715.522 of the Revised Code be 7
enacted to read as follows: 8

Sec. 3715.01. (A) As used in this chapter: 9

(1) "Person" means an individual, partnership, 10
corporation, or association. 11

(2) "Food" means: 12

(a) Articles used for food or drink for humans or animals; 13

(b) Chewing gum; 14

(c) Articles used for components of any such articles. 15

(3) "Drug" means:	16
(a) Articles recognized in the United States pharmacopoeia and national formulary, or any supplement to them;	17 18
(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;	19 20 21
(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals;	22 23 24
(d) Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories.	25 26 27
(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:	28 29 30 31 32 33 34
(a) Recognized in the United States pharmacopoeia and national formulary, or any supplement to them;	35 36
(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;	37 38 39
(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	40 41 42 43

being metabolized for the achievement of any of its principal 44
intended purposes. 45

(5) "Cosmetic" means: 46

(a) Articles intended to be rubbed, poured, sprinkled, or 47
sprayed on, introduced into, or otherwise applied to the human 48
body or any part thereof for cleansing, beautifying, promoting 49
attractiveness, or altering the appearance; 50

(b) Articles intended for use as a component of any such 51
article, except that "cosmetic" does not include soap. 52

(6) "Cosmetic ingredient" means a chemical or mixture used 53
as a component in the manufacture of a cosmetic product, as 54
described in 21 C.F.R. 700.3(e). 55

(7) "Cosmetic product" means a finished cosmetic, the 56
manufacture of which has been completed. 57

(8) "Cosmetic animal testing" means the internal or 58
external application or exposure of any cosmetic product or 59
cosmetic ingredient to the skin, eyes, or any other organ or 60
extremity of a live, nonhuman vertebrate for the purpose of 61
evaluating the safety or efficacy of a cosmetic product or a 62
cosmetic ingredient or nonfunctional constituent for use in a 63
cosmetic product. 64

(9) "Cosmetic manufacturer" means any person whose name 65
appears on the label of a cosmetic product pursuant to the 66
requirements of 21 C.F.R. 701.12. 67

(10) "Cosmetic supplier" means any person that provides, 68
directly or through a third party, a cosmetic ingredient used by 69
a cosmetic manufacturer in the formulation of a cosmetic 70
product. 71

(11) "Nonfunctional constituent" means any incidental ingredient, as defined in 21 C.F.R. 701.3. 72
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(12) "Label" means a display of written, printed, or graphic matter upon the immediate container, exclusive of package liners, of any article. 74
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Any word, statement, or other information required by this chapter to appear on the label must appear on the outside container or wrapper, if any, of the retail package of the article, or the label must be easily legible through the outside container or wrapper. 77
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~~(7)~~(13) "Labeling" means all labels and other written, printed, or graphic matter: 82
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- (a) Upon an article or any of its containers or wrappers; 84
- (b) Accompanying such article. 85

~~(8)~~(14) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics. 86
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~~(9)~~(15) "New drug" means: 91

(a) Any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; 92
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(b) Any drug the composition of which is such that the drug, as a result of investigation to determine its safety for use under such conditions, has become so recognized, but that 97
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has not, other than in an investigation, been used to a material 100
extent or for a material time under such conditions. 101

~~(10)~~ (16) "Contaminated with filth" applies to any food, 102
drug, device, or cosmetic that has not been protected as far as 103
may be necessary by all reasonable means from dust, dirt, and 104
all foreign or injurious substances. 105

~~(11)~~ (17) "Honey" means the nectar and saccharine 106
exudation of plants that has been gathered, modified, and stored 107
in a honeycomb by honeybees. 108

~~(12)~~ (18) "Finished dosage form" means the form of a drug 109
that is, or is intended to be, dispensed or administered to 110
humans or animals and requires no further manufacturing or 111
processing other than packaging, reconstituting, or labeling. 112

~~(13)~~ ~~(a)~~ (19) (a) "Manufacture" means the planting, 113
cultivating, harvesting, processing, making, preparing, or 114
otherwise engaging in any part of the production of a drug by 115
propagating, compounding, converting, or processing, either 116
directly or indirectly by extracting from substances of natural 117
origin, or independently by means of chemical synthesis, or by a 118
combination of extraction and chemical synthesis, and includes 119
the following: 120

(i) Any packaging or repackaging of the drug or labeling 121
or relabeling of its container, the promotion and marketing of 122
the drug, and other activities incident to production; 123

(ii) The preparation and promotion of commercially 124
available products from bulk compounds for resale by pharmacies, 125
licensed health professionals authorized to prescribe drugs, or 126
other persons. 127

(b) "Manufacture" does not include the preparation, 128

compounding, packaging, or labeling of a drug by a pharmacist as	129
an incident to either of the following:	130
(i) Dispensing a drug in the usual course of professional	131
practice;	132
(ii) Providing a licensed health professional authorized	133
to prescribe drugs with a drug for the purpose of administering	134
to patients or for using the drug in treating patients in the	135
professional's office.	136
(14) <u>(20)</u> "Dangerous drug" has the same meaning as in	137
section 4729.01 of the Revised Code.	138
(15) <u>(21)</u> "Generically equivalent drug" means a drug that	139
contains identical amounts of the identical active ingredients,	140
but not necessarily containing the same inactive ingredients,	141
that meets the identical compendial or other applicable standard	142
of identity, strength, quality, and purity, including potency,	143
and where applicable, content uniformity, disintegration times,	144
or dissolution rates, as the prescribed brand name drug and the	145
manufacturer or distributor holds, if applicable, either an	146
approved new drug application or an approved abbreviated new	147
drug application unless other approval by law or from the	148
federal food and drug administration is required.	149
No drug shall be considered a generically equivalent drug	150
for the purposes of this chapter if it has been listed by the	151
federal food and drug administration as having proven	152
bioequivalence problems.	153
(16) <u>(22)</u> "Licensed health professional authorized to	154
prescribe drugs" and "prescriber" have the same meanings as in	155
section 4729.01 of the Revised Code.	156
(17) <u>(23)</u> "Home" means the primary residence occupied by	157

the residence's owner, on the condition that the residence 158
contains only one stove or oven used for cooking, which may be a 159
double oven, designed for common residence usage and not for 160
commercial usage, and that the stove or oven be operated in an 161
ordinary kitchen within the residence. 162

~~(18)~~ (24) "Potentially hazardous food" means a food that 163
is natural or synthetic, to which any of the following apply: 164

(a) It has a pH level greater than 4.6 when measured at 165
seventy-five degrees fahrenheit or twenty-four degrees celsius. 166

(b) It has a water activity value greater than 0.85. 167

(c) It requires temperature control because it is in a 168
form capable of supporting the rapid and progressive growth of 169
infectious or toxigenic microorganisms, the growth and toxin 170
production of clostridium botulinum, or in the case of raw 171
shell eggs, the growth of salmonella enteritidis. 172

~~(19)~~ (25) "Cottage food production operation" means a 173
person who, in the person's home, produces food items that are 174
not potentially hazardous foods, including bakery products, 175
jams, jellies, candy, fruit butter, and similar products 176
specified in rules adopted pursuant to section 3715.025 of the 177
Revised Code. 178

~~(20)~~ (26) "Biological product" means, except as provided 179
in section 3715.011 of the Revised Code, a drug that is a 180
biological product, as defined on ~~the effective date of this~~ 181
~~amendment~~ March 21, 2017, in subsection (i) of section 351 of 182
the "Public Health Service Act," 42 U.S.C. 262(i). 183

~~(21)~~ (27) "Interchangeable biological product" means, 184
except as provided in section 3715.011 of the Revised Code, both 185
of the following: 186

(a) A biological product that, on ~~the effective date of~~ 187
~~this amendment~~ March 21, 2017, has been determined by the United 188
States food and drug administration to meet the standards for 189
interchangeability set forth in subsection (k) of section 351 of 190
the "Public Health Service Act," 42 U.S.C. 262(k), as amended, 191
and has been licensed under that subsection; 192

(b) A biological product that, prior to ~~the effective date~~ 193
~~of this amendment~~ March 21, 2017, was determined by the United 194
States food and drug administration to be therapeutically 195
equivalent as set forth in its publication titled "Approved Drug 196
Products with Therapeutic Equivalence Evaluations." 197

(B) For the purposes of sections 3715.52 to 3715.72 of the 198
Revised Code: 199

(1) If an article is alleged to be misbranded because the 200
labeling is misleading, or if an advertisement is alleged to be 201
false because it is misleading, then in determining whether the 202
labeling or advertisement is misleading, there shall be taken 203
into account, among other things, not only representations made 204
or suggested by statement, word, design, device, sound, or in 205
any combination thereof, but also the extent to which the 206
labeling or advertisement fails to reveal facts material in the 207
light of such representations or material with respect to 208
consequence which may result from the use of the article to 209
which the labeling or advertisement relates under the conditions 210
of use prescribed in the labeling or advertisement thereof or 211
under such conditions of use as are customary or usual. 212

(2) The provisions regarding the selling of food, drugs, 213
devices, or cosmetics include the manufacture, production, 214
processing, packing, exposure, offer, possession, and holding of 215
any such article for sale; and the sale, dispensing, and giving 216

of any such article, and the supplying or applying of any such 217
articles in the conduct of any food, drug, or cosmetic 218
establishment. The provisions do not prohibit a licensed health 219
professional authorized to prescribe drugs from administering or 220
personally furnishing a drug or device to a patient. 221

(3) The representation of a drug, in its labeling or 222
advertisement, as an antiseptic is a representation that it is a 223
germicide, except in the case of a drug purporting to be, or 224
represented as, an antiseptic for inhibitory use as a wet 225
dressing, ointment, dusting powder, or other use that involves 226
prolonged contact with the body. 227

(4) Whenever jurisdiction is vested in the director of 228
agriculture or the state board of pharmacy, the jurisdiction of 229
the board shall be limited to the sale, offering for sale, 230
giving away, delivery, or dispensing in any manner of drugs at 231
the wholesale and retail levels or to the consumer and shall be 232
exclusive in the case of such sale, offering for sale, giving 233
away, delivery, or dispensing in any manner of drugs at the 234
wholesale and retail levels or to the consumer in any place 235
where prescriptions are dispensed or compounded. 236

(5) To assist in effectuating the provisions of those 237
sections, the director of agriculture or state board of pharmacy 238
may request assistance or data from any government or private 239
agency or individual. 240

Sec. 3715.025. (A) A cottage food production operation 241
shall not process acidified foods, low acid canned foods, or 242
potentially hazardous foods. 243

(B) The director of agriculture shall adopt rules in 244
accordance with Chapter 119. of the Revised Code specifying the 245

food items a cottage food production operation may produce that 246
are in addition to the food items identified by name in division 247
~~(A) (19)~~ (A) (25) of section 3715.01 of the Revised Code. The 248
director shall not adopt rules that permit a cottage food 249
production operation to produce any food that is a potentially 250
hazardous food. 251

Sec. 3715.522. (A) Subject to division (B) of this 252
section, no cosmetic manufacturer shall knowingly sell, offer 253
for sale, or deliver at retail or to a consumer, a cosmetic 254
product developed or manufactured using cosmetic animal testing 255
that was conducted or contracted for by the cosmetic 256
manufacturer, or any cosmetic supplier of the cosmetic 257
manufacturer. 258

(B) Division (A) of this section does not apply to any of 259
the following: 260

(1) Animal testing conducted outside of the United States 261
in order to comply with a requirement of a foreign regulatory 262
authority, provided that no evidence derived from such testing 263
was relied upon by the cosmetic manufacturer or cosmetic 264
supplier to substantiate the safety of the cosmetic product 265
sold, offered, or delivered in this state; 266

(2) Animal testing conducted for any cosmetic or cosmetic 267
ingredient subject to regulation under Chapter V of the "Federal 268
Food, Drug, and Cosmetic Act," 21 U.S.C. 351, et seq.; 269

(3) Animal testing conducted for an ingredient intended to 270
be used in a product other than a cosmetic and conducted 271
pursuant to a requirement of the department of agriculture, 272
state board of pharmacy, or a federal, state, or foreign 273
regulatory authority, provided that no evidence derived from 274

such testing was relied upon to substantiate the safety of the 275
cosmetic product sold, offered, or delivered in this state, 276
unless all of the following apply: 277

(a) There is no non-animal method or strategy recognized 278
by the department of agriculture, state board of pharmacy, a 279
federal agency, or the organization for economic co-operation 280
and development for the relevant safety endpoints for the 281
cosmetic ingredient; 282

(b) There is documented evidence that animal testing was 283
conducted with the intent to use the ingredient in a product 284
other than a cosmetic; 285

(c) The ingredient has been used in a product other than 286
cosmetics at least twelve months before the cosmetic 287
manufacturer or cosmetic supplier relied on the results of 288
animal testing. 289

(4) Animal testing requested, required, or conducted by 290
the department of agriculture, state board of pharmacy, or a 291
federal or state regulatory authority, if all of the following 292
apply: 293

(a) There is no non-animal method or strategy recognized 294
by the department of agriculture, state board of pharmacy, a 295
federal agency, or the organization for economic co-operation 296
and development for the relevant safety endpoints for the 297
cosmetic ingredient or nonfunctional constituent; 298

(b) There is a reasonable probability that the ingredient 299
or nonfunctional constituent poses a specific and serious 300
adverse human health risk and the need to conduct an animal test 301
is justified and supported by a detailed research protocol 302
proposed as the basis for the evaluation of the cosmetic 303

ingredient or nonfunctional constituent; 304

(c) The cosmetic ingredient is widely used and cannot be 305
replaced by another cosmetic ingredient capable of performing a 306
similar function. 307

(5) A cosmetic, if the cosmetic in its final form was 308
tested on animals before the effective date of this enactment, 309
even if the cosmetic is manufactured on or after that date, 310
provided that no new animal testing in violation of this section 311
is conducted on the cosmetic by, or on behalf of, the cosmetic 312
manufacturer; 313

(6) A cosmetic ingredient, if the cosmetic ingredient was 314
tested on animals before the effective date of this enactment, 315
even if the cosmetic ingredient is manufactured on or after that 316
date, provided that no new animal testing in violation of this 317
section is conducted on the cosmetic ingredient by, or on behalf 318
of, the cosmetic manufacturer; 319

(7) A cosmetic manufacturer or cosmetic supplier 320
reviewing, assessing, or retaining evidence from animal testing. 321

(C) No county, township, or municipal corporation, 322
including a county that has adopted a charter under Ohio 323
Constitution, Article X, Section 3, and a township that adopts a 324
limited home rule government, shall prohibit or enforce a 325
prohibition relating to cosmetic animal testing other than the 326
prohibitions set forth in this section or identical 327
prohibitions, which may be adopted by ordinance or resolution of 328
the board of county commissioners, board of township trustees, 329
or legislative authority of the municipal corporation. 330

Sec. 3715.99. (A) Whoever violates section 3715.13 or 331
3715.38 of the Revised Code is guilty of a minor misdemeanor. 332

(B) Whoever violates section 3715.22, 3715.25, or 3715.27 333
of the Revised Code is guilty of a misdemeanor of the fourth 334
degree. 335

(C) Whoever violates section 3715.23 or 3715.34 of the 336
Revised Code is guilty of a misdemeanor of the second degree. 337

(D) Whoever violates section 3715.52 or 3715.65 of the 338
Revised Code is guilty of a misdemeanor of the fourth degree on 339
a first offense; on each subsequent offense, the person is 340
guilty of a misdemeanor of the second degree. 341

(E) Whoever violates section 3715.521 of the Revised Code 342
is guilty of a minor misdemeanor. A violation of that section 343
occurs on a daily basis, not according to the number of times 344
per day that an expired drug, baby food, or infant formula is 345
sold, offered for sale, or delivered at retail or to the 346
consumer. Each day of violation is a separate offense. 347

(F) The director of agriculture or the director's designee 348
shall impose a civil penalty, in accordance with Chapter 119. of 349
the Revised Code, not exceeding five thousand dollars on whoever 350
violates section 3715.522 of the Revised Code. The director 351
shall impose an additional penalty of one thousand dollars for 352
each day the violation continues. The director shall deposit the 353
penalty to the credit of the cosmetic animal testing prevention 354
fund, which is hereby created in the state treasury. All money 355
in the fund shall be used to offset the costs incurred by the 356
department of agriculture in enforcing section 3715.522 of the 357
Revised Code. 358

Sec. 3717.01. As used in this chapter: 359

(A) "Ohio uniform food safety code" means the food safety 360
and related standards adopted under section 3717.05 of the 361

Revised Code.	362
(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.	363 364 365 366
(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.	367 368 369 370 371 372 373
As used in this division:	374
(1) "Retail" means the sale of food to a person who is the ultimate consumer.	375 376
(2) "Prepared" means any action that affects a food, including receiving and maintaining it at the temperature at which it was received.	377 378 379
(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 a licensing period.	380 381 382 383
(E) "Temporary retail food establishment" means a retail food establishment 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 3717.23 of the Revised Code.	384 385 386 387 388
(F) "Food service operation" means a place, location,	389

site, or separate area where food intended to be served in 390
individual portions is prepared or served for a charge or 391
required donation. As used in this division, "served" means a 392
response made to an order for one or more individual portions of 393
food in a form that is edible without washing, cooking, or 394
additional preparation and "prepared" means any action that 395
affects a food other than receiving or maintaining it at the 396
temperature at which it was received. 397

Except when expressly provided otherwise, "food service 398
operation" includes a catering food service operation, food 399
delivery sales operation, mobile food service operation, 400
seasonal food service operation, temporary food service 401
operation, and vending machine location. 402

(G) "Catering food service operation" means a food service 403
operation where food is prepared for serving at a function or 404
event held at an off-premises site, for a charge determined on a 405
per-function or per-event basis. 406

(H) "Food delivery sales operation" means a food service 407
operation from which individual portions of food are ordered by 408
a customer, prepared at another food service operation or a 409
retail food establishment, and delivered to the customer by a 410
person other than an employee of the food service operation or 411
retail food establishment that prepared the food. 412

(I) "Mobile food service operation" means a food service 413
operation that is operated from a movable vehicle, portable 414
structure, or watercraft and that routinely changes location, 415
except that if the operation remains at any one location for 416
more than forty consecutive days, the operation is no longer a 417
mobile food service operation. "Mobile food service operation" 418
includes a food service operation that does not remain at any 419

one location for more than forty consecutive days and serves, in 420
a manner consistent with division (F) of this section, only 421
frozen desserts; beverages, nuts, popcorn, candy, or similar 422
confections; bakery products identified in section 911.01 of the 423
Revised Code; or any combination of those items. 424

(J) "Seasonal food service operation" means a food service 425
operation, other than a mobile food service operation, that is 426
operated for not more than six months in a licensing period. 427

(K) "Temporary food service operation" means a food 428
service operation that is operated at an event for not more than 429
five consecutive days, except when operated for more than five 430
consecutive days pursuant to division (E) (2) of section 3717.43 431
of the Revised Code. 432

(L) "Vending machine location" means an area or room where 433
one or more vending machines are installed and operated, except 434
that if the machines within an area are separated by more than 435
one hundred fifty feet, each area separated by that distance 436
constitutes a separate vending machine location. As used in this 437
division, "vending machine" means a self-service device that 438
automatically dispenses on the insertion of currency, tokens, or 439
similar means a predetermined unit serving of food, either in 440
bulk or in package, without having to be replenished after each 441
use. 442

(M) "Board of health" means a board of health of a city or 443
general health district or the authority having the duties of a 444
board of health under section 3709.05 of the Revised Code. 445

(N) "Government entity" means this state, a political 446
subdivision of this state, another state, or a political 447
subdivision or other local government body of another state. 448

- (O) "Licensor" means one of the following: 449
- (1) A board of health approved under section 3717.11 of 450
the Revised Code; 451
- (2) The director of agriculture acting pursuant to section 452
3717.11 of the Revised Code with respect to the licensing of 453
retail food establishments; 454
- (3) The director of health acting pursuant to section 455
3717.11 of the Revised Code with respect to the licensing of 456
food service operations. 457
- (P) "Licensing period" means the first day of March to the 458
last day of February of the next succeeding year. 459
- (Q) "Mobile retail food establishment" means a retail food 460
establishment that is operated from a movable vehicle or other 461
portable structure, and that routinely changes location, except 462
that if the establishment operates from any one location for 463
more than forty consecutive days, the establishment is no longer 464
a mobile retail food establishment. 465
- (R) "Unprocessed," when used with respect to fruits and 466
vegetables, means that the fruits and vegetables are not 467
processed beyond merely rough trimming and rinsing. 468
- (S) "Cottage food production operation" has the same 469
meaning as in ~~division (A) (19) of~~ section 3715.01 of the Revised 470
Code. 471
- Section 2.** That existing sections 3715.01, 3715.025, 472
3715.99, and 3717.01 of the Revised Code are hereby repealed. 473