

As Introduced

**132nd General Assembly
Regular Session
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S. B. No. 233

**Senator Thomas
Cosponsors: Senators Brown, Tavares**

A BILL

To amend section 3715.01 of the Revised Code to
allow a cottage food production operator to use
a firebrick oven located on a patio at the
operator's residence for purposes of the cottage
food production operation.

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

Section 1. That section 3715.01 of the Revised Code be
amended to read as follows:

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

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

(2) "Food" means:

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

(b) Chewing gum;

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

(3) "Drug" means:

(a) Articles recognized in the United States pharmacopoeia and national formulary, or any supplement to them;	16 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 sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance;	46 47 48 49
(b) Articles intended for use as a component of any such article, except that "cosmetic" does not include soap.	50 51
(6) "Label" means a display of written, printed, or graphic matter upon the immediate container, exclusive of package liners, of any article.	52 53 54
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.	55 56 57 58 59
(7) "Labeling" means all labels and other written, printed, or graphic matter:	60 61
(a) Upon an article or any of its containers or wrappers;	62
(b) Accompanying such article.	63
(8) "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.	64 65 66 67
(9) "New drug" means:	68
(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	69 70 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 available products from bulk compounds for resale by pharmacies, licensed health professionals authorized to prescribe drugs, or other persons.

(b) "Manufacture" does not include the preparation, compounding, packaging, or labeling of a drug by a pharmacist as an incident to either of the following:

(i) Dispensing a drug in the usual course of professional practice;

(ii) Providing a licensed health professional authorized to prescribe drugs with a drug for the purpose of administering to patients or for using the drug in treating patients in the professional's office.

(14) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(15) "Generically equivalent drug" means a drug that contains identical amounts of the identical active ingredients, but not necessarily containing the same inactive ingredients, that meets the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency, and where applicable, content uniformity, disintegration times, or dissolution rates, as the prescribed brand name drug and the manufacturer or distributor holds, if applicable, either an approved new drug application or an approved abbreviated new drug application unless other approval by law or from the federal food and drug administration is required.

No drug shall be considered a generically equivalent drug for the purposes of this chapter if it has been listed by the federal food and drug administration as having proven

bioequivalence problems.	130
(16) "Licensed health professional authorized to prescribe drugs" and "prescriber" have the same meanings as in section 4729.01 of the Revised Code.	131 132 133
(17) "Home" means the primary residence occupied by the residence's owner, on the condition that the residence contains only one <u>has either or both of the following:</u>	134 135 136
(a) <u>One stove or oven used for cooking, which may be a double oven, that is designed for common residence usage and not for commercial usage,</u> and that the stove or oven be <u>is</u> operated in an ordinary kitchen within the residence;	137 138 139 140
(b) <u>One firebrick oven that is used for cooking and is located on a patio appurtenant to the primary residence.</u>	141 142
(18) "Potentially hazardous food" means a food that is natural or synthetic, to which any of the following apply:	143 144
(a) It has a pH level greater than 4.6 when measured at seventy-five degrees fahrenheit or twenty-four degrees celsius.	145 146
(b) It has a water activity value greater than 0.85.	147
(c) It requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of clostridium botulinum, or in the case of raw shell eggs, the growth of salmonella enteritidis.	148 149 150 151 152
(19) "Cottage food production operation" means a person who, in the person's home, produces food items that are not potentially hazardous foods, including bakery products, jams, jellies, candy, fruit butter, and similar products specified in rules adopted pursuant to section 3715.025 of the Revised Code.	153 154 155 156 157

(20) "Biological product" means, except as provided in 158
section 3715.011 of the Revised Code, a drug that is a 159
biological product, as defined ~~on the effective date of this~~ 160
~~amendment~~ March 21, 2017, in subsection (i) of section 351 of 161
the "Public Health Service Act," 42 U.S.C. 262(i). 162

(21) "Interchangeable biological product" means, except as 163
provided in section 3715.011 of the Revised Code, both of the 164
following: 165

(a) A biological product that, ~~on the effective date of~~ 166
~~this amendment~~ March 21, 2017, has been determined by the United 167
States food and drug administration to meet the standards for 168
interchangeability set forth in subsection (k) of section 351 of 169
the "Public Health Service Act," 42 U.S.C. 262(k), as amended, 170
and has been licensed under that subsection; 171

(b) A biological product that, ~~prior to the effective date~~ 172
~~of this amendment~~ March 21, 2017, was determined by the United 173
States food and drug administration to be therapeutically 174
equivalent as set forth in its publication titled "Approved Drug 175
Products with Therapeutic Equivalence Evaluations." 176

(B) For the purposes of sections 3715.52 to 3715.72 of the 177
Revised Code: 178

(1) If an article is alleged to be misbranded because the 179
labeling is misleading, or if an advertisement is alleged to be 180
false because it is misleading, then in determining whether the 181
labeling or advertisement is misleading, there shall be taken 182
into account, among other things, not only representations made 183
or suggested by statement, word, design, device, sound, or in 184
any combination thereof, but also the extent to which the 185
labeling or advertisement fails to reveal facts material in the 186

light of such representations or material with respect to 187
consequence which may result from the use of the article to 188
which the labeling or advertisement relates under the conditions 189
of use prescribed in the labeling or advertisement thereof or 190
under such conditions of use as are customary or usual. 191

(2) The provisions regarding the selling of food, drugs, 192
devices, or cosmetics include the manufacture, production, 193
processing, packing, exposure, offer, possession, and holding of 194
any such article for sale; and the sale, dispensing, and giving 195
of any such article, and the supplying or applying of any such 196
articles in the conduct of any food, drug, or cosmetic 197
establishment. The provisions do not prohibit a licensed health 198
professional authorized to prescribe drugs from administering or 199
personally furnishing a drug or device to a patient. 200

(3) The representation of a drug, in its labeling or 201
advertisement, as an antiseptic is a representation that it is a 202
germicide, except in the case of a drug purporting to be, or 203
represented as, an antiseptic for inhibitory use as a wet 204
dressing, ointment, dusting powder, or other use that involves 205
prolonged contact with the body. 206

(4) Whenever jurisdiction is vested in the director of 207
agriculture or the state board of pharmacy, the jurisdiction of 208
the board shall be limited to the sale, offering for sale, 209
giving away, delivery, or dispensing in any manner of drugs at 210
the wholesale and retail levels or to the consumer and shall be 211
exclusive in the case of such sale, offering for sale, giving 212
away, delivery, or dispensing in any manner of drugs at the 213
wholesale and retail levels or to the consumer in any place 214
where prescriptions are dispensed or compounded. 215

(5) To assist in effectuating the provisions of those 216

sections, the director of agriculture or state board of pharmacy 217
may request assistance or data from any government or private 218
agency or individual. 219

Section 2. That existing section 3715.01 of the Revised 220
Code is hereby repealed. 221