

Chapter 3715
Ohio Food, Drug, Cosmetic and Device Law

3715.01 Definitions.

(A) As used in this chapter:

- (1) "Public health council" means the public health council established by section 3701.33 of the Revised Code.
- (2) "Person" means an individual, partnership, corporation, or association.
- (3) "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.
- (4) "Drug" means:
 - (a) Articles recognized in the United States pharmacopoeia and national formulary, or any supplement to them;
 - (b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
 - (c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals;
 - (d) Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories.
- (5) "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:
 - (a) Recognized in the United States pharmacopoeia and national formulary, or any supplement to them;
 - (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;
 - (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.

(6) "Cosmetic" means:

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

(7) "Label" means a display of written, printed, or graphic matter upon the immediate container, exclusive of package liners, of any article.

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.

(8) "Labeling" means all labels and other written, printed, or graphic matter:

- (a) Upon an article or any of its containers or wrappers;
- (b) Accompanying such article.

(9) "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.

(10) "New drug" means:

- (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;
- (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 has not, other than in an investigation, been used to a material extent or for a material time under such conditions.

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

(12) "Honey" means the nectar and saccharine exudation of plants that has been gathered, modified, and stored in a honeycomb by honeybees.

(13) "Finished dosage form" means the form of a drug that is, or is intended to be, dispensed or administered to humans or animals and requires no further manufacturing or processing other than

packaging, reconstituting, or labeling.

(14)(a) "Manufacture" means the planting, cultivating, harvesting, processing, making, preparing, or otherwise engaging in any part of the production of a drug by propagating, compounding, converting, or processing, either directly or indirectly by extracting from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes the following:

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

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

(16) "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.

(17) "Licensed health professional authorized to prescribe drugs" and "prescriber" have the same meanings as in section 4729.01 of the Revised Code.

(18) "Home" means the primary residence occupied by the residence's owner, on the condition that the residence contains only one stove or oven used for cooking, which may be a double oven, designed for common residence usage and not for commercial usage, and that the stove or oven be operated in an ordinary kitchen within the residence.

(19) "Potentially hazardous food" means a food that is natural or synthetic, to which any of the following apply:

- (a) It has a pH level greater than 4.6 when measured at seventy-five degrees Fahrenheit or twenty-four degrees Celsius.

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

(20) "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.

(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 under such conditions of use as are customary or usual.
- (2) The provisions regarding the selling of food, drugs, devices, or cosmetics include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment. The provisions do not prohibit a licensed health professional authorized to prescribe drugs from administering or personally furnishing a drug or device to a patient.
- (3) The representation of a drug, in its labeling or advertisement, as an antiseptic is a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use that involves prolonged contact with the body.
- (4) Whenever jurisdiction is vested in the director of agriculture or the state board of pharmacy, the jurisdiction of the board shall be limited to the sale, offering for sale, giving away, delivery, or dispensing in any manner of drugs at the wholesale and retail levels or to the consumer and shall be exclusive in the case of such sale, offering for sale, giving away, delivery, or dispensing in any manner of drugs at the wholesale and retail levels or to the consumer in any place where prescriptions are dispensed or compounded.
- (5) To assist in effectuating the provisions of those sections, the director of agriculture or state board of pharmacy may request assistance or data from any government or private agency or individual.

3715.02 Definitions and Standards For Food Items and Establishments; Rules for Sample Analyses; Illness Investigations.

(A) The director of agriculture shall adopt rules in accordance with Chapter 119. of the Revised Code that establish, when otherwise not established by a law of this state, definitions for a food or class of food and

standards for the following items as they pertain to the food or class of food:

- (1) Quality, identity, purity, grade, and strength;
- (2) Packaging and labeling;
- (3) Food processing equipment;
- (4) Processing procedures;
- (5) Fill of containers.

The standards and definitions, where applicable, shall conform to the standards for foods adopted by the United States department of agriculture and the United States food and drug administration. Portions of Titles 7, 9, and 21 of the Code of Federal Regulations or the regulations adopted for the enforcement of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 et seq., as amended, may be adopted as rules by referencing the federal regulations, subject to the approval of the joint committee on agency rule review.

In adopting rules that establish definitions and standards of identity for a food or class of food in which only a limited number of optional ingredients are permitted, the director shall designate the optional ingredients that must be listed on the label.

- (B) The director shall adopt rules in accordance with Chapter 119. of the Revised Code that establish procedures for the performance of sample analyses of food, food additives, and food packaging materials. The circumstances under which a sample analysis may be required include the following:
- (1) When a food, food additive, or food packaging material is the subject of a consumer complaint;
 - (2) When requested by a consumer after a physician has isolated an organism from the consumer as the physician's patient;
 - (3) When a food, food additive, or food packaging material is suspected of having caused an illness;
 - (4) When a food, food additive, or food packaging material is suspected of being adulterated or misbranded;
 - (5) When a food, food additive, or food packaging material is subject to verification of food labeling and standards of identity;
 - (6) At any other time the director considers a sample analysis necessary.
- (C) In foodborne illness investigations, the director of agriculture shall cooperate and consult with the laboratory maintained by the department of health under section 3701.22 of the Revised Code.
- (D) The director or the director's designee shall do all of the following:
- (1) Inspect drugs, food, or drink manufactured, stored, or offered for sale in this state;

(2) Prosecute or cause to be prosecuted each person engaged in the unlawful manufacture or sale of an adulterated drug or article of food or drink, in violation of law;

(3) Enforce all laws against fraud, adulteration, or impurities in drugs, foods, or drinks and unlawful labeling within this state.

(E) The director may appoint or contract for one or more qualified persons to enforce the provisions of this chapter.

3715.021 Food Processing Establishments; Definition.

(A) As used in this section, "food processing establishment" means a premises or part of a premises where food is processed, packaged, manufactured, or otherwise held or handled for distribution to another location or for sale at wholesale. "Food processing establishment" includes the activities of a bakery, confectionery, cannery, bottler, warehouse, or distributor, and the activities of an entity that receives or salvages distressed food for sale or use as food. A "food processing establishment" does not include a cottage food production operation; a processor of maple syrup who boils sap when a minimum of seventy-five per cent of the sap used to produce the syrup is collected directly from trees by that processor; a processor of sorghum who processes sorghum juice when a minimum of seventy-five per cent of the sorghum juice used to produce the sorghum is extracted directly from sorghum plants by that processor; or a beekeeper who jars honey when a minimum of seventy-five per cent of the honey is from that beekeeper's own hives.

(B) The director of agriculture shall adopt rules in accordance with Chapter 119. of the Revised Code that establish, when otherwise not established by the Revised Code, standards and good manufacturing practices for food processing establishments, including the facilities of food processing establishments and their sanitation. The rules shall conform with or be equivalent to the standards for foods established by the United States food and drug administration in Title 21 of the Code of Federal Regulations.

A business or that portion of a business that is regulated by the department of agriculture under Chapter 917. or 918. of the Revised Code is not subject to regulation under this section as a food processing establishment.

3715.022 Cottage Food Products, Maple Syrup, Sorghum, and Honey Sampling.

(A) All food products, including those produced and packaged by a cottage food production operation, and all packaged maple syrup, sorghum, and honey, are subject to food sampling conducted by the director of agriculture, or a representative the director authorizes, to determine if a food product is misbranded or adulterated. A component of the food sampling conducted under this section may include the performance of sample analyses in accordance with section 3715.02 of the Revised Code.

The director of agriculture shall adopt rules as the director considers necessary to establish standards for food sampling and procedures for administration of this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

(B) Labeling requirements do not apply to fruit butter produced at a festival or celebration, if the

festival or celebration is organized by a political subdivision of this state and the fruit butter is sold during the festival or celebration from the production site.

3715.023. Labeling: Cottage Food Products, Maple Syrup, Sorghum, Honey.

- (A) A cottage food production operation and a maple syrup or sorghum processor and beekeeper described in division (A) of section 3715.021 of the Revised Code shall label each of their food products and include the following information on the label of each of their food products:
- (1) The name and address of the business of the cottage food production operation, processor, or beekeeper;
 - (2) The name of the food product;
 - (3) The ingredients of the food product, in descending order of predominance by weight;
 - (4) The net weight and volume of the food product;
 - (5) In the case of a cottage food production operation, the following statement in ten-point type:
"This product is home produced."
- (B) Food products identified and labeled in accordance with division (A) of this section are acceptable food products that a retail food establishment or food service operation licensed under Chapter 3717. of the Revised Code may offer for sale or use in preparing and serving food.

3715.024. Voluntary Inspection: Maple Syrup, Honey, Sorghum

- (A) A maple syrup or sorghum processor and beekeeper described in division (A) of section 3715.021 of the Revised Code may request that the director of agriculture conduct a voluntary inspection of the processor's or beekeeper's facilities. After the inspection is completed, if the inspector determines that the facilities comply with the rules adopted by the director pursuant to division (B) of this section, the processor or beekeeper may place on the label required under section 3715.023 of the Revised Code a seal of conformity and inspection of the department of agriculture.
- (B) The director shall adopt rules in accordance with Chapter 119. of the Revised Code that establish the following:
- (1) Standards that maple syrup or sorghum processors and beekeepers must satisfy in order to be permitted to place on the label of their food products a seal of conformity and inspection of the director, as described in division (A) of this section;
 - (2) The seal of conformity and inspection to be used for purposes described in division (A) of this section.

3715.025. Prohibitions Concerning Cottage Food Operations.

- (A) A cottage food production operation shall not process acidified foods, low acid canned foods, or potentially hazardous foods.

- (B) The director of agriculture shall adopt rules in accordance with Chapter 119. of the Revised Code specifying the food items a cottage food production operation may produce that are in addition to the food items identified by name in division (A)(20) of section 3715.01 of the Revised Code. The director shall not adopt rules that permit a cottage food production operation to produce any food that is a potentially hazardous food.

3715.03 Right of Entry to Make Inspection.

The director of agriculture, in performing duties under this chapter, may enter a creamery, factory, store salesroom, pharmacy, laboratory, or other place where the director believes or has reason to believe drugs, food, or drink is made, prepared, dispensed, sold, or offered for sale; examine the books therein; and open a cask, tub, jar, bottle, or other package containing or supposed to contain a drug or an article of food or drink and examine the contents or cause them to be examined and analyzed.

3715.07 Standards for Flavoring Extracts.

A flavoring extract is adulterated within the meaning of sections 3715.01 to 3715.37, inclusive, of the Revised Code, if, when sold under or by any one of the following names it differs from the standard fixed therefor by this section:

- (A) Almond extract is the flavoring extract prepared from oil of bitter almonds, free from hydrocyanic acid, and shall contain not less than one per cent by volume of oil of bitter almonds.
- (B) Anise extract is the flavoring extract prepared from oil of anise, and shall contain not less than three per cent by volume of oil of anise.
- (C) Celery seed extract is the flavoring extract prepared from celery seed or the oil of celery seed, or both, and shall contain not less than three-tenths per cent by volume of oil of celery seed.
- (D) Cassia extract is the flavoring extract prepared from oil of cassia, and shall contain not less than two per cent by volume of oil of cassia.
- (E) Cinnamon extract is the flavoring extract prepared from oil of cinnamon, and shall contain not less than two per cent by volume of oil of cinnamon.
- (F) Clove extract is the flavoring extract prepared from oil of cloves, and shall contain not less than two percent by volume of oil of cloves.
- (G) Ginger extract is the flavoring extract prepared from ginger, and shall contain in each one hundred cubic centimeters the alcohol-soluble matters from not less than twenty grams of ginger.
- (H) Lemon extract is the flavoring extract prepared from oil of lemon or from lemon peel, or both, and shall contain not less than five per cent by volume of oil of lemon.
- (I) Terpeneless extract of lemon is the flavoring extract prepared by shaking oil of lemon with dilute alcohol, or by dissolving terpeneless oil of lemon in dilute alcohol, and shall contain not less than two-tenths per cent by weight of citral derived from oil of lemon.

- (J) Nutmeg extract is the flavoring extract prepared from oil of nutmeg, and shall contain not less than two per cent by volume of oil of nutmeg.
- (K) Orange extract is the flavoring extract prepared from oil of orange or from orange peel, or both, and shall contain not less than five per cent by volume of oil of orange.
- (L) Terpeneless extract of orange is the flavoring extract prepared by shaking oil of orange with dilute alcohol, or by dissolving terpeneless oil of orange in dilute alcohol and shall correspond in flavoring strength to orange extract.
- (M) Peppermint extract is the flavoring extract prepared from oil of peppermint or from peppermint, or both, and shall contain not less than three per cent by volume of oil of peppermint.
- (N) Rose extract is the flavoring extract prepared from otto of roses, with or without rose petals, and shall contain not less than four-tenths per cent by volume of otto of roses.
- (O) Savory extract is the flavoring extract prepared from oil of savory or from savory, or both, and shall contain not less than thirty-five hundredths per cent by volume of oil of savory.
- (P) Spearmint extract is the flavoring extract prepared from oil of spearmint or from spearmint, or both, and shall contain not less than three per cent by volume of oil of spearmint.
- (Q) Star anise extract is the flavoring extract prepared from oil of star anise, and shall contain not less than three per cent by volume of oil of star anise.
- (R) Sweet basil extract is the flavoring extract prepared from oil of sweet basil or from sweet basil, or both, and shall contain not less than one-tenth per cent by volume of oil of sweet basil.
- (S) Sweet marjoram extract or marjoram extract is the flavoring extract prepared from the oil of marjoram or from marjoram, or both, and shall contain not less than one per cent by volume of oil of marjoram.
- (T) Thyme extract is the flavoring extract prepared from oil of thyme or from thyme, or both, and shall contain not less than two-tenths per cent by volume of oil of thyme.
- (U) Tonka extract is the flavoring extract prepared from tonka bean, with or without sugar or glycerine, and shall contain not less than one-tenth per cent by weight of coumarin extracted from the tonka bean, together with a corresponding proportion of the other soluble matters thereof.
- (V) Vanilla extract is the flavoring extract prepared from vanilla bean, with or without sugar or glycerine, and shall contain in one hundred cubic centimeters the soluble matters from not less than ten grams of the vanilla bean.
- (W) Wintergreen extract is the flavoring extract prepared from oil of wintergreen, and shall contain not less than three per cent by volume of oil of wintergreen.

All of said flavoring extracts shall be a solution in ethyl alcohol of proper strength of the sapid and odorous principles derived from an aromatic plant, or parts of the plant, and shall conform in name to the plant used in its preparation.

3715.13 Sale of Diphtheria Antitoxin.

No person shall sell any diphtheria antitoxin produced and distributed by the department of health.

3715.14 Prohibition Against Sale of Unlabeled Canned Fruits and Vegetables by a Dealer.

No dealer in preserved or canned fruits, vegetables, or other articles of food, shall offer them for sale unless they bear a mark to indicate the grade or quality, and the name and address of the person, firm, or corporation packing or dealing therein, except such as are brought from foreign countries.

3715.15 Prohibition Against Sale of Unlabeled Canned Fruits and Vegetables by a Packer or Manufacturer.

No packer or manufacturer of preserved or canned fruits, vegetables, or other articles of food, shall offer them for sale unless they bear a mark to indicate the grade or quality, and the name and address of the person, firm, or corporation packing or dealing therein, except such as are brought from foreign countries.

3715.16 Prohibition Against Falsely Labeling Fruit or Vegetable Packages.

No person shall falsely stamp or label cans or jars containing preserved fruit, vegetables, or other articles of food or knowingly permit such false stamping or labeling.

3715.17 Prohibition Against Selling Falsely Labeled Fruit or Vegetables.

No person shall sell or offer to sell cans or jars containing preserved fruit, vegetables, or other articles of food, which are falsely stamped or labeled.

3715.171 Perishable Foods Sale Date Label.

As used in this section:

"Quality assurance period" means the period of time following the completion of normal manufacturing, processing, and packaging procedures during which a food product subjected to normal conditions of exposure will maintain conformity with all of the characteristics normally associated with the food product and will provide the benefits for which the food product is normally purchased. Food product characteristics include, but are not limited to, taste, texture, smell, nutritional value, and reaction value with other food products if used as an ingredient with other food products.

"Sale date" means the date by which the manufacturer, processor, or packager of a packaged food product recommends that the food product be sold for consumption based on the food product's quality assurance period.

(A) Except as provided in division (B) of this section, no person shall knowingly sell or offer to sell in this state any packaged perishable food product that has a quality assurance period of thirty days or less,

unless the package is clearly marked by the packager with its sale date. The sale date shall be legible and understandable to the consumer. The director of agriculture shall make rules in accordance with Chapter 119. of the Revised Code establishing the manner in which the sale date shall be affixed to food products.

The director is authorized to investigate complaints, to determine whether the sale date for food products, as determined by the manufacturer, processor, or packager, is false or misleading to consumers. If the director finds, upon reasonable cause, that the sale date as determined by the manufacturer, processor, or packager, is false or misleading to the consumer, the director after reasonable notice and hearing, in accordance with Chapter 119. of the Revised Code, shall establish the sale date for said product.

- (B) The provisions of this section do not apply to fresh fruits and vegetables or to meat, including poultry, whether packaged or un packaged, nor do they apply to packaged perishable food products when sold or offered for sale at any place of business where less than one hundred thousand dollars of all products were sold during the preceding year.
- (C) To ensure that a uniform system of determining the useful product life of perishable food products for sale within the state is established, persons complying with this section and the rules established pursuant thereto are exempt from any local ordinances or rules pertaining to the quality assurance period of food products or the manner in which the quality assurance period and perishability of food products are to be disclosed.

3715.18 Manufacturer or Packer Must Attach Label to "Soaked" Goods.

No manufacturer or packer shall manufacture, sell, or offer to sell "soaked" goods put up from products dried before canning, without plainly marking them with an adhesive label having on its face the word "soaked," in letters not less in size than two line pica of solid and legible type.

3715.19 Vendor Must Attach Label to "Soaked" Goods.

No vendor shall sell or offer to sell "soaked" goods put up from products dried before canning, without plainly marking them with an adhesive label having on its face the word "soaked," in letters not less in size than two line pica of solid and legible type.

3715.20 Prosecution.

The board of health of a city health district or of a general health district shall prosecute a person, firm, or corporation which it has reason to believe has violated sections 3715.14 to 3715.19, inclusive, of the Revised Code; and, after deducting the costs of trial, retain the residue of fines recovered for the use of such board.

3715.22 Prohibition Against Slaughter or Sale For Human Consumption of Calf Less Than Four Weeks Old; Confiscation of Carcass.

No dealer, slaughterer, or processor of meat or meat products for human consumption shall kill or have in his

possession for the purpose of killing, a calf less than four weeks old or have in his possession the carcass of a calf not sufficiently mature to be fit for human consumption. The carcass of such calf may be confiscated by an authorized agent of the United States department of agriculture, the department of agriculture of Ohio, or by an authorized agent of the department of health of this state or any of its political subdivisions.

3715.23 Manufacture and Sale of Adulterated Candy; Sample for Analysis.

No person shall manufacture for sale, sell, or offer for sale, candy with an admixture of terra alba, barytes, talc, or other mineral substance, or with poisonous colors or flavors or other ingredients deleterious or detrimental to health.

No manufacturer of or dealer in candy, shall refuse, upon demand and a tender of payment therefor, to furnish a sample thereof for analysis.

Whoever violates this section shall pay all expenses incurred in inspecting and analyzing such adulterated candy. All candy manufactured for sale, sold, or offered for sale in violation of this section shall be forfeited and destroyed under the direction of the court.

3715.24 Maple Product Standards and Grades.

(A) As used in this section and section 3715.25 of the Revised Code:

- (1) "Grade" means standards for grades of maple syrup adopted by the United States department of agriculture and accepted by the director of agriculture or grades as defined in rules adopted by the director.
- (2) "Maple products" means maple syrup, maple sugar, maple cream, or any other product in which the sugar content is entirely derived from pure maple sap and to which no other sweetener has been added.
- (3) "Maple sap" means the unprocessed liquid derived from the maple tree of the acer species.
- (4) "Maple sugar" or "maple concrete" means the solid, crystalline products derived from pure maple sap.
- (5) "Maple syrup" means the unadulterated liquid food derived by concentration and heat treatment of pure maple sap or by reconstituting maple sugar or maple concrete with water to a density of not less than sixty-six degrees on the brix* scale at sixty-eight degrees fahrenheit** and any permitted optional ingredients.
- (6) "Package" means a container, equal to or less than five gallons in volume, intended to be sold to individuals or commercial businesses for use without further processing or repackaging of the contents.

(B) The director of agriculture shall adopt rules in accordance with Chapter 119. of the Revised Code that establish voluntary grades, authorized optional ingredients, standards for fill of containers, and standards of weight for the sale of maple products in this state and that specify the analytical tests to be used for determining compliance with those voluntary grade requirements.

- (C) The director shall develop and maintain laboratory facilities, equipment, and procedures sufficient to determine whether maple syrup complies with the requirements relative to standards and grades in this chapter and the rules adopted under it.

3715.25 Prohibitions Concerning Maple Products.

- (A) No person shall manufacture, offer for sale, possess with intent to sell, sell, or deliver a maple product that is adulterated as described in section 3715.59 of the Revised Code or is misbranded as described in section 3715.60 of the Revised Code.
- (B) No person shall offer for sale, possess with intent to sell, sell, or deliver an adulteration of a maple product in a package having the word "maple" or a compound thereof, as the name or part of the name of the contents of the package, or in a package bearing a device or illustration suggestive of a maple product or the manufacture of a maple product.
- (C) No person shall sell, deliver, offer for sale, or possess with intent to sell a packaged maple product without a label that complies with rules adopted under section 3715.02 of the Revised Code.
- (D) No person shall represent an imitation maple product, as defined in rules adopted under section 3715.02 of the Revised Code, as a maple product.

3715.27 Cider Manufacturing and Labeling.

- (A) As used in this section, "cider" means the unfermented juice, obtained by mechanically expressing the juice from sound, mature, non-citrus fruit, from which is removed excess pulp and seeds, other than embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice. The cider may contain natural or artificial citric acid, preservatives authorized by rules adopted under section 3715.02 of the Revised Code, or a combination thereof.
- (B) For the manufacture of apple cider, a mechanical washing and scrubbing device shall be used to remove orchard soil and dirt from the fruit prior to crushing. This device shall be equipped with automatic scrubbing brushes and a means to chlorinate the water used as the washing liquid.
- (C) A complete label that complies with rules adopted under section 3715.02 of the Revised Code shall be placed on each package of cider designed for sale to the ultimate consumer.
- (D) No person shall fail to comply with division (B) or (C) of this section.

3715.28 Vinegar.

Vinegar shall be made wholly from the fruit or grain from which it purports, or is represented, to be made and shall not contain a foreign substance or less than four per cent, by weight, of absolute acetic acid.

3715.29 Cider or Apple Vinegar.

Vinegar manufactured, offered or exposed for sale, sold, or delivered, or in the possession of a person with intent to sell or deliver, under the name of cider vinegar, apple vinegar, or any compounding of the word "cider" or "apple" as the name or part of the name of vinegar, shall be the product made by the alcoholic and subsequent acetous fermentations of the juice of apples, and shall not contain any foreign substance, drugs, or acids, and is laevorotatory. It shall contain not less than four grams of acetic acid, not less than one and six-tenths grams of apple solids of which not more than fifty per cent are reducing sugars, and not less than twenty-five hundredths grams of apple ash in one hundred cubic centimeters at a temperature of twenty degrees centigrade. The water-soluble ash from one hundred cubic centimeters, at a temperature of twenty degrees centigrade, of the vinegar shall contain not less than ten milligrams of phosphoric acid (P2 O5) which shall require not less than thirty cubic centimeters of decinormal acid to neutralize its alkalinity.

3715.30 Wine or Grape Vinegar.

Vinegar manufactured, offered or exposed for sale, sold, or delivered, or in the possession of a person with intent to sell or deliver, under the name of wine vinegar or grape vinegar, shall be the product made by the alcoholic and subsequent acetous fermentations of the juice of grapes, and shall contain, in one hundred cubic centimeters, at a temperature of twenty degrees centigrade, not less than four grams of acetic acid, not less than one gram of grape solids, and not less than thirteen-hundredths grams of grape ash.

3715.31 Malt Vinegar.

Vinegar manufactured, offered or exposed for sale, sold, or delivered, or in the possession of a person with intent to sell or deliver, under the name of malt vinegar shall be the product made by the alcoholic and subsequent acetous fermentations, without distillation, of an infusion of barley malt or cereals whose starch has been converted by malt, is dextrorotatory, and shall contain in one hundred cubic centimeters, at a temperature of twenty degrees centigrade, not less than four grams of acetic acid, not less than two grams of solids, and not less than two-tenths grams of ash. The water-soluble ash from one hundred cubic centimeters, at a temperature of twenty degrees centigrade, of the vinegar shall contain not less than nine milligrams of phosphoric acid (P2 Q5) which shall require not less than four cubic centimeters of decinormal acid to neutralize its alkalinity.

3715.32 Distilled Vinegar.

Vinegar manufactured, offered or exposed for sale, sold, or delivered, or in the possession of a person with intent to sell or deliver, under the name of distilled vinegar, shall be the product made wholly or in part by the acetous fermentation of dilute distilled alcohol and shall contain in one hundred cubic centimeters, at a temperature of twenty degrees centigrade, not less than four grams of acetic acid, and shall be free from coloring matter added during or after distillation and from coloring other than that imparted to it by distillation. Vinegar made wholly or in part from distilled liquor shall be branded "distilled vinegar," and free from coloring matter added during or after distillation and from color other than that imparted to it by distillation.

3715.33 Fermented Vinegar.

Vinegar made by fermentation and oxidation without the intervention of distillation shall be branded "fermented vinegar" with the name of the fruit or substance from which it is made. Fermented vinegar, not otherwise provided for in sections 3715.28 to 3715.36, inclusive, of the Revised Code, and not being distilled vinegar as defined in section 3715.32 of the Revised Code, shall contain not less than two per cent by weight, upon full evaporation at the temperature of boiling water, of solids, contained in the fruit or grain or substance from which such vinegar is fermented, and not less than two and one-half-tenths of one per cent ash or mineral matter, the product of the material from which such vinegar is manufactured.

3715.34 Injurious Ingredients in Vinegar; Brands.

No person shall manufacture for sale, offer for sale, or have in his possession with intent to sell, vinegar found upon proper test to contain a preparation of lead, copper, sulphuric or other mineral acid, or other ingredients injurious to health.

The head of a cask, barrel, package, or keg containing vinegar shall be branded with the name and residence of the manufacturer and shall conform to sections 3715.32 and 3715.33 of the Revised Code.

3715.35 Brands on Casks of Cider Vinegar.

A person making or manufacturing cider vinegar, not a domestic manufacturer of cider or cider vinegar, shall brand on each head of each cask, barrel, or keg containing such vinegar, the name and residence of the manufacturer, the date when manufactured, and the words "cider vinegar." Vinegar shall not be branded "fruit vinegar" unless it is made wholly from apples, grapes, or other fruits.

3715.36 Prohibition Against Selling Vinegar not Made or Branded in Compliance with Law.

No person shall manufacture for sale, sell, deliver, or offer or expose for sale, or have in his possession with intent to sell or deliver, vinegar not made in compliance with sections 3715.28 to 3715.35, inclusive, of the Revised Code, or contained in packages not branded in compliance with such sections.

No person shall violate sections 3715.28 to 3715.36, inclusive, of the Revised Code.

Whoever violates this section shall pay all necessary costs and expenses incurred in inspecting and analyzing the vinegar.

3715.37 Branding of Cider Vinegar by Manufacturing Farmer.

Sections 3715.28 to 3715.36, inclusive, of the Revised Code apply to any farmer who manufactures for sale in any one year more than twenty-five barrels of pure cider or fruit vinegar. Such vinegar must be branded "domestic cider vinegar," and marked with the name of such farmer and the date of its manufacture.

3715.38 Labeling of Honey.

No person shall sell, offer, or expose for sale any product that is:

- (A) In the semblance of honey and labeled, advertised, or otherwise represented to be honey if it is not honey;
- (B) In the semblance of honey and contains a label that applies the word "imitation" to the product, regardless of whether it contains any honey;
- (C) In the semblance of honey and is a blend of honey and other ingredients that contains a label with the word "honey," or any picture, drawing, or other representation implying honey, when such word, picture, drawing, or representation is more prominently displayed than the word "blend" or other word clearly implying the existence of other ingredients.

3715.52 Prohibitions.

- (A) The following acts and causing them are prohibited:
 - (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
 - (2) The adulteration or misbranding of any food, drug, device, or cosmetic;
 - (3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;
 - (4) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code;
 - (5) The dissemination of any false advertisement;
 - (6) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by section 3715.70 of the Revised Code;
 - (7) The giving of a guaranty or undertaking that is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in this state from whom the person received in good faith the food, drug, device, or cosmetic;
 - (8) The removal or disposal of a detained or embargoed article in violation of section 3715.55 or 3715.551 [3715.55.1] of the Revised Code;
 - (9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if the act is done while the article is held for sale and results in the article being misbranded;
 - (10) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted pursuant to sections 3715.52 to 3715.72 of the Revised Code;
 - (11) The using, on the labeling of any drug or in any advertisement relating to a drug, of any representation or suggestion that any application with respect to the drug is effective under section 3715.65 of the Revised Code or that the drug complies with the provisions of that section;

(12) The using by any person to the person's own advantage, or revealing, other than to the director of agriculture or to the courts when relevant in any judicial proceeding under sections 3715.52 to 3715.72 of the Revised Code, any information acquired under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, concerning any information that as a trade secret is entitled to protection;

(13) The issuance by the manufacturer, packer, or distributor of a dangerous drug of any advertisements, catalogues, or price lists, except those lists specifically designed for disseminating price change information, that do not contain in clearly legible form the name and place of business of the manufacturer who mixed the final ingredients and, if different, the manufacturer who produced the drug in its finished dosage form and, if different, the packer or distributor.

(B)(1) No person at a flea market shall sell, offer for sale, or knowingly permit the sale of any of the following products:

(a) Baby food, infant formula, or similar products;

(b) Any drug, cosmetic, or device;

(c) Any product on which is printed or stamped an expiration date or a date recommended by the manufacturer as either the last day on which the product should be offered for sale or the last day on which the product should be used.

(2) Division (B)(1) of this section does not apply to a person who keeps available for public inspection an identification card identifying the person as an authorized representative of the manufacturer or distributor of any drug, cosmetic, or device, as long as the card is not false, fraudulent, or fraudulently obtained.

(3) Division (B)(1)(c) of this section does not apply to a person or governmental entity that is licensed as a retail food establishment or food service operation under Chapter 3717. of the Revised Code or is listed in division (B)(9) or (12) of section 3717.42 of the Revised Code.

(4) As used in division (B)(1) of this section, "flea market" means any location, other than a permanent retail store, at which space is rented or otherwise made available to others for the conduct of business as transient or limited vendors as defined in section 5739.17 of the Revised Code.

3715.521 Sale or Delivery of Expired Drug, Infant Formula or Baby Food.

No person shall sell, offer for sale, or deliver at retail or to the consumer, any of the following:

(A) Any drug after the expiration date required by 21 C.F.R. 211.137;

(B) Any infant formula after the "use by" date required by 21 C.F.R. 107.20;

(C) Any baby food after any expiration date, "use by" date, or sale date required by state or federal law or marked on the container by the manufacturer, processor, or packager.

3715.53 Injunctions.

In addition to the remedies provided and irrespective of whether or not there exists an adequate remedy at law, the director of agriculture or the state board of pharmacy is hereby authorized to apply to the court of common pleas in the county wherein any of the provisions of section 3715.52 of the Revised Code are being violated for a temporary or permanent injunction restraining any person from committing the violation.

3715.54 Exceptions to Liability.

- (A) No person shall be subject to the penalties prescribed in section 3715.99 of the Revised Code for violating division (A)(1) or (3) of section 3715.52 of the Revised Code if the person established a guaranty or undertaking signed by, and containing the name and address of, the person residing in this state from whom the person received in good faith the article, to the effect that the article is not adulterated or misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code.
- (B) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination of false advertisement.

3715.55 Detention or Embargo in Case of Violation; Condemnation or Destruction.

- (A) As used in this section, "expired" means:
 - (1) In the case of a drug, that the expiration date required by 21 C.F.R. 211.137 has passed;
 - (2) In the case of infant formula, the "use by" date required by 21 C.F.R. 107.20 has passed;
 - (3) In the case of baby food, that any expiration date, "use by" date, or sale date established by state or federal law or marked on the container by the manufacturer, processor, or packager has passed.
- (B) Whenever the director of agriculture or the state board of pharmacy finds or has cause to believe, that any food, drug, device, or cosmetic is adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, or that a drug, infant formula, or baby food is expired, the director or board shall affix to the article a tag or other appropriate marking, giving notice that the article is, or is suspected of being, adulterated, misbranded, or expired and has been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by the director or the board or the court. No person may remove or dispose of a detained or embargoed article by sale or otherwise without such permission.
- (C) When an article detained or embargoed has been found by the director or board to be adulterated, misbranded, or expired, the director or board shall petition the municipal or county court in whose jurisdiction the article is detained or embargoed for an order for condemnation of the article. When the director or the board has not found within ten days that an article so detained or embargoed is adulterated, misbranded, or expired, the director or board shall remove the tag or other marking.
- (D) If the court finds that a detained or embargoed article is adulterated, misbranded, or expired, the article

shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of the director or the board, and all court costs, fees, storage, and other proper expenses shall be taxed against the claimant of the article or the claimant's agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the article shall be so labeled or processed, has been executed, may by order direct that the article be delivered to the claimant thereof for labeling or processing under the supervision of the director or the board. The expense of supervision shall be paid by the claimant. The bond shall be returned to the claimant of the article on representation to the court by the director or the board that the article is no longer in violation of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, and that the expenses of supervision have been paid.

- (E) Whenever the director finds in any room, building, vehicle of transportation, or other structure, any meat, sea food, poultry, vegetable, fruit, or other perishable articles that are unsound, or contain any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the articles are declared to be a nuisance, and the director shall forthwith condemn or destroy the articles, or in any other manner render the articles unsalable as human food.

3715.55.1 Embargo of Food.

- (A) As used in this section, "board of health," "retail food establishment," and "food service operation" have the same meanings as in section 3717.01 of the Revised Code.
- (B) The embargoing of a food may be performed by a board of health approved under section 3717.11 of the Revised Code to serve as the licenser of retail food establishments or food service operations, the director of health acting under section 3717.11 of the Revised Code as the licenser of food service operations, or a representative authorized to act on behalf of the board of health or director of health.

The director of agriculture shall adopt rules in accordance with Chapter 119. of the Revised Code specifying the conditions under which a food may be embargoed under this section and the procedures that must be followed when that action is taken.

3715.56 Attorney General, Prosecuting Attorney or City Director of Law to Assist in Enforcement.

The attorney general, prosecuting attorney, or city director of law to whom the director of agriculture or the state board of pharmacy reports any violation of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, shall cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. The director of agriculture, before reporting any violation of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to any such attorney for the institution of a criminal proceeding, shall give the person against whom the proceeding is contemplated appropriate notice and an opportunity to present testimony before the director, either orally or in writing, in person, or by attorney, with regard to the contemplated proceeding.

3715.57 Written Notice or Warning for Minor Violations.

Nothing in sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, shall be construed as requiring the

director of agriculture or the state board of pharmacy to report minor violations for the institution of proceedings under sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, whenever the director or board believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

3715.59 When Food is Adulterated.

Food is adulterated within the meaning of sections 3715.01, 3715.02, 3715.022 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:

- (A) It bears or contains any poisonous or deleterious substance that may render it injurious to health; but in case the substance is not an added substance, the food shall not be considered adulterated if the quantity of the substance in the food does not ordinarily render it injurious to health.
- (B) It bears or contains any added poisonous or added deleterious substance that is unsafe within the meaning of section 3715.62 of the Revised Code.
- (C) It consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.
- (D) It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health.
- (E) It is the product of a diseased animal or an animal that has died otherwise than by slaughter, or an animal that has been fed upon the uncooked offal from a slaughterhouse.
- (F) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
- (G) Any valuable constituent has been, in whole or in part, omitted or abstracted from the food.
- (H) Any substance has been substituted wholly or in part for the food.
- (I) Damage or inferiority has been concealed in any manner.
- (J) Any substance has been added to or mixed or packed with the food so as to increase its bulk or weight, reduce its quality or strength, or make it appear better or of greater value than it is.
- (K) It is confectionery and it bears or contains any alcohol or nonnutritive article or substance other than harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of one per cent, harmless natural wax not in excess of four-tenths of one per cent, harmless natural gum, or pectin, except that this division shall not apply to any confectionery by reason of its containing less than one-half of one per cent by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.
- (L) It bears or contains a coal-tar color other than one from a batch certified under authority of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

(M) It has been processed or produced in violation of section 3715.025 of the Revised Code.

3715.60 Misbranded Food.

Food is misbranded within the meaning of sections 3715.01, 3715.02, 3715.022, and 3715.52 to 3715.72 of the Revised Code, if:

- (A) Its labeling is false or misleading in any particular.
- (B) It is offered for sale under the name of another food.
- (C) Its container is so made, formed, or filled as to be misleading.
- (D) It is an imitation of another food, unless its label bears in type of uniform size and prominence, the word "imitation," and immediately thereafter the name of the food imitated.
- (E) When it is in package form, it does not bear a label containing:
 - (1) The name and place of business of the manufacturer, packer, or distributor;
 - (2) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that reasonable variations shall be permitted, and exemptions as to small packages shall be established by rules adopted by the director of agriculture.
 - (3) In the case of food subject to section 3715.023 of the Revised Code, the information specified in that section.
- (F) Any word, statement, or other information required by or under authority of sections 3715.01, 3715.02, and 3715.52 to 3715.72 of the Revised Code, to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (G) It purports to be, or is represented as, a food for which a definition and standard of identity have been prescribed by statute, or by any rule adopted under an existing statute, or by rule as provided by section 3715.02 of the Revised Code, unless:
 - (1) It conforms to such definition and standard.
 - (2) Its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such statute or rules, the common names of optional ingredients, other than spices, flavoring, and coloring, present in such food.
- (H) It purports to be or is represented as:
 - (1) A food for which a standard of quality has been prescribed by rule as provided by section 3715.02 of the Revised Code and its quality falls below the standard unless its label bears, in the manner and form that the rules specify, a statement that it falls below the standard;

(2) A food for which a standard or standards of fill of container have been prescribed by rule as provided by section 3715.02 of the Revised Code, and it falls below the standard of fill of container applicable thereto, unless its label bears, in the manner and form that the rules specify, a statement that it falls below the standard.

(I) It is not subject to the provisions of division (G) of this section, unless it bears labeling clearly giving:

(1) The common or usual name of the food, if any;

(2) In case it is fabricated from two or more ingredients, the common or usual name of each ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each; provided, that, to the extent that compliance with the requirements of division (I)(2) of this section is impractical or results in deception or unfair competition, exemptions shall be established by rules adopted by the director; and provided that these requirements shall not apply to any carbonated beverage of which a full and correct statement of the ingredients, to the extent prescribed by division (I)(2) of this section, has been filed under oath with the director.

(J) It purports to be or is represented to be for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is provided by rules proposed by the director and adopted by the public health council, as necessary, in order to fully inform purchasers as to its value for such uses.

(K) It bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; provided, that to the extent that compliance with the requirements of this division is impracticable, exemptions shall be established by rules proposed by the director and adopted by the public health council.

3715.61 Powers of Director.

(A) Whenever the director of agriculture finds after investigation that the distribution in this state of any class of food may, by reason of contamination with microorganisms during manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered commerce, and in such case only, he shall propose regulations for adoption by the public health council providing for the issuance, to manufacturers, processor[s], or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the director as provided by such regulations.

(B) The director is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the director shall, immediately after prompt hearing and on inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the

permit, as originally issued, or as amended.

- (C) The director shall have access to any factory or establishment, the operator of which holds a permit from the director for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

3715.62 Unsafe Food.

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be unsafe for purposes of the application of division (B) of section 3715.59 of the Revised Code, but when such substance is so required or cannot be so avoided, the director of agriculture shall propose regulations for adoption by the public health council limiting the quantity therein or thereon to such extent as the director finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of division (B) of section 3715.59 of the Revised Code. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of division (A) of section 3715.59 of the Revised Code. In determining the quantity of such added substance to be tolerated in or on different articles of food, the director shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

3715.63 When Drug or Device is Adulterated.

A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:

- (A) It consists, in whole or in part, of any filthy, putrid, or decomposed substance.
- (B) It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.
- (C) It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
- (D) It is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch certified under authority of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.
- (E) It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set

forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary.

(F) It is not subject to the provisions of division (E) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess.

(G) It is a drug and any substance has been:

- (1) Mixed or packed with the drug so as to reduce the drug's quality or strength;
- (2) Substituted wholly or in part for the drug.

3715.64 Misbranded Drug or Device.

(A) A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:

(1) Its labeling is false or misleading in any particular.

(2) It is in package form and does not bear a label containing both of the following:

(a) In clearly legible form, the name and place of business of the manufacturer, packer, or distributor;

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; but reasonable variations shall be permitted, and exemptions as to small packages shall apply as established by rules adopted by the director of agriculture or state board of pharmacy.

(3) It is a dangerous drug and does not bear a label containing in clearly legible form the name and place of business of the manufacturer of the finished dosage form and, if different, the packer or distributor.

(4) It is a dangerous drug in finished solid oral dosage form and it does not have clearly and prominently marked or imprinted on it an individual symbol, company name, national drug code number or other number, words, letters, or any combination thereof, identifying the drug and its manufacturer or distributor. This requirement does not apply to drugs that are compounded by a licensed pharmacist. The manufacturer or distributor of each such drug shall make available to the state board of pharmacy descriptive material identifying the mark or imprint used by the manufacturer or distributor. The board shall provide this information to all poison control centers in this state. Upon application by a manufacturer or distributor, the board may exempt a drug from the requirements of this division on the grounds that marking or imprinting the drug is not feasible because of its size, texture, or other unique characteristic.

(5) Any word, statement, or other information that is required by or under authority of sections 3715.01

and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

- (6) It is a drug and it is not designated solely by a name recognized in the United States pharmacopoeia and national formulary, or any supplement to them, unless its label bears:
 - (a) The common or usual name of the drug, if any;
 - (b) In case it is fabricated from two or more ingredients, the common or usual name of each active ingredient the drug contains, including the kind and quantity or proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanalid, acetophenetidin, aminopyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances; but to the extent that compliance with these requirements is impracticable, exemptions shall apply as established by rules adopted by the director of agriculture or state board of pharmacy.
- (7) Its labeling does not bear the following:
 - (a) Adequate directions for use of the drug or device, except that when compliance with this requirement is not necessary for a particular drug or device to protect the public health, the director shall adopt rules exempting the drug or device from the requirement;
 - (b) Adequate warnings against use in those pathological conditions or by children when its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, presented in a manner and form as necessary for the protection of users.
- (8) It purports to be a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and it is not packaged and labeled as prescribed in those compendiums, except that the method of packing may be modified with the consent of the director of agriculture. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary.
- (9) It has been found by the director of agriculture to be a drug liable to deterioration, unless it is packaged in the form and manner, and its label bears a statement of precautions, as required by rules adopted by the director as necessary for the protection of public health. No rule shall be established for any drug recognized in the United States pharmacopoeia and national formulary, or any supplements to them, until the director has informed the appropriate bodies charged with the revision of those compendiums of the need for packaging or labeling requirements and those bodies have failed within a reasonable time to prescribe such requirements.
- (10)(a) It is a drug and its container is so made, formed, or filled as to be misleading.

- (b) It is an imitation of another drug.
 - (c) It is offered for sale under the name of another drug.
 - (d) The drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, is neither the brand or drug prescribed nor a generically equivalent drug.
- (11) It is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.
- (12) It is a drug intended for human use to which the following apply:
- (a) Because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, the drug is not safe for use except under the supervision of a licensed health professional authorized to prescribe drugs;
 - (b) The drug is limited by an effective application under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, to use under professional supervision by a licensed health professional authorized to prescribe drugs, unless it is dispensed only:
 - (i) Upon a written or electronic prescription;
 - (ii) Upon an oral prescription, which is reduced promptly to writing by the pharmacist;
 - (iii) By refilling a prescription if refilling is authorized by the prescriber either in the original prescription or by oral order, which is promptly reduced to writing by the pharmacist.
- (B) Any drug dispensed pursuant to a written, electronic, or oral prescription of a licensed health professional authorized to prescribe drugs shall be exempt from the requirements of division (A) of this section, except divisions (A)(1) and (10) of this section, if the drug bears a label containing the name and address of the dispenser, the serial number and the date the prescription is dispensed, the name of the prescriber, the name of the patient, and, if stated in the prescription, the directions for use and cautionary statements. Unless the prescription directions prohibit labeling, the label shall include the brand name of the drug dispensed. If the drug dispensed has no brand name, the generic name and the distributor of the finished dosage form shall be included.

3715.65 Application Concerning New Drug.

- (A) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless:
- (1) An application with respect to the drug has become effective under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.
 - (2) If the drug is not subject to the "Federal Food, Drug, and Cosmetic Act," the drug has been tested and found to be safe for use under the conditions prescribed, recommended, or suggested in its labeling,

and, prior to selling the drug or offering it for sale, there has been filed with the director of agriculture an application setting forth all of the following:

- (a) Full reports of investigations that have been made to show whether or not the drug is safe for use;
 - (b) A full list of the articles used as components of the drug;
 - (c) A full statement of the drug's composition;
 - (d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;
 - (e) Samples, as the director may require, of the drug and the articles used as components of the drug;
 - (f) Specimens of the labeling proposed to be used for the drug.
- (B) An application provided for in division (A)(2) of this section shall become effective sixty days after it is filed, except that if the director finds after due notice to the applicant and after giving the applicant an opportunity for a hearing, that the drug is not safe for use under the conditions prescribed, recommended, or suggested in the drug's proposed labeling, the director shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective. The order may be revoked by the director.
- (C) This section does not apply to the following:
- (1) A drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs provided that the drug is plainly labeled "For investigational use only";
 - (2) A drug sold in this state at any time prior to the enactment of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, or introduced into interstate commerce at any time prior to the enactment of the "Federal Food, Drug, and Cosmetic Act";
 - (3) Any drug that is licensed under the "Public Health Service Act," 58 Stat. 682 (1944), 42 U.S.C.A. 301, as amended, or under the "Virus-Serum-Toxin Act," 37 Stat. 832 (1913), 21 U.S.C.A. 151, as amended.

3715.66 Adulterated Cosmetics.

- (A) A cosmetic is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
- (1) It bears or contains any poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling or advertisement of the cosmetic, or under conditions of use that are customary or usual, except that this provision does not apply to coal-tar hair dye if both of the following conditions are met:

- (a) The label bears the following legend conspicuously displayed thereon: "Caution-This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."
 - (b) The labeling bears adequate directions for preliminary testing.
- (2) It contains, in whole or in part, any filthy, putrid, or decomposed substance.
 - (3) It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
 - (4) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
 - (5) It is not a hair dye and it bears or contains a coal-tar color other than one from a batch certified under authority of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.
- (B) For purposes of divisions (A)(1) and (5) of this section, "hair dye" does not include eyelash dye or eyebrow dye.

3715.67 Misbranded Cosmetics.

A cosmetic is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72, inclusive, of the Revised Code, if:

- (A) Its labeling is false or misleading in any particular.
- (B) It is in package form unless it bears a label containing:
 - (1) The name and place of business of the manufacturer, packer, or distributor;
 - (2) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the director of agriculture.
- (C) Any word, statement, or other information required by or under authority of sections 3715.01 and 3715.52 to 3715.72, inclusive, of the Revised Code, to appear on the label or labeling is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (D) Its container is so made, formed, or filled as to be misleading.

3715.68 False Advertising.

- (A) An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular.
- (B) For the purpose of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, tuberculosis, tumors, typhoid, uremia, venereal disease, is also false, except that no advertisement not in violation of division (A) of this section is false under this division if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary profession, or appears only in the scientific periodicals of these professions; provided, that whenever the director of agriculture determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the director shall propose regulations for adoption by the public health council authorizing the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the director may deem necessary in the interests of public health; provided, that this division shall not be construed as indicating that self-medication for diseases other than those named in this section is safe or efficacious.

3715.69 Rules for Enforcement.

The authority to adopt rules for the enforcement of section 3715.02, divisions (E), (G), (H), and (I) of section 3715.60, division (A)(2) of section 3715.64, and section 3715.67 of the Revised Code is vested in the director of agriculture. The authority to adopt rules for the enforcement of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, excluding divisions (E), (G), (H), and (I) of section 3715.60, division (A)(2) of section 3715.64, and section 3715.67 of the Revised Code, is vested in the director of agriculture or the state board of pharmacy. The rules adopted in so far as practicable shall conform with the regulations promulgated under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

3715.70 Right of Entry for Inspection; Examination of Samples.

- (A) The director of agriculture or the state board of pharmacy shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce, or to enter any vehicle being used to transport or hold foods, drugs, devices, or cosmetics in commerce, for the following purposes:
- (1) To inspect the factory, warehouse, establishment, or vehicle to determine if any of the provisions of sections 3715.01 or 3715.52 to 3715.72 of the Revised Code, are being violated;
 - (2) To secure samples of specimens of any food, drug, device, or cosmetic.
- (B) The director or the board shall make or cause to be made examinations of samples secured under the provisions of this section to determine whether or not any provisions of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code are being violated.

3715.71 Publication of Reports of Judgments; Dispensing of Information.

The director of agriculture or the state board of pharmacy may cause to be published from time to time reports summarizing all judgments, decrees, and court orders that have been rendered under sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, including the nature of the charge and the disposition thereof.

The director or board may also cause to be disseminated any information regarding food, drugs, devices, and cosmetics that the director or board deems necessary in the interest of public health and the protection of the consumer against fraud.

Nothing in this section shall be construed to prohibit the director or board from collecting, reporting, and illustrating the results of investigations conducted by the director or board.

3715.72 Administration; Exceptions.

- (A) Sections 3715.01 and 3715.52 to 3715.71, inclusive, of the Revised Code shall be governed by and be administered in accordance with sections 119.01 to 119.13, inclusive, of the Revised Code.
- (B) Sections 3715.01 and 3715.52 to 3715.71, inclusive, and section 3715.99, of the Revised Code, do not apply when such sections are in conflict with sections 923.41 to 923.55, inclusive, and section 923.99 of the Revised Code.
- (C) Sections 3715.52 to 3715.71, inclusive, of the Revised Code do not permit the manufacture, sale, or offering for sale, of any food, drug, cosmetic, or device otherwise prohibited by any provision of the Revised Code or by any regulations promulgated pursuant to any provision of the Revised Code; nor do sections 3715.52 to 3715.71, inclusive, of the Revised Code or any regulations thereunder, prohibit the sale or offering for sale, of any food, drug, cosmetic, or device through any outlet where such items are now permitted by any provisions of the Revised Code to be sold or offered for sale.

3715.73 Disposition of Fines and Forfeited Bonds.

- (A) All fines or forfeited bonds assessed and collected under prosecution by the director of agriculture or prosecution commenced by the director in enforcement of this chapter shall, within thirty days, be paid to the director and by the director paid into the state treasury.
- (B) All fines or forfeited bonds assessed and collected under prosecution by the state board of pharmacy or prosecution commenced by the board in enforcement of this chapter shall, within thirty days, be paid to the executive director of the board and by the executive director paid into the state treasury.

3715.74 Governor may Declare Public Health State of Emergency as to Adulterated Consumer Product.

(A) As used in this section:

- (1) "Adulterated" means adulterated as determined under section 3715.59 or 3715.63 of the Revised Code.

(2) "Consumer product" means any food or drink that is consumed by humans and any medicine, including a prescription drug, that is consumed or used by humans.

(3) "Retailer" means a place of business that offers consumer products for sale to the general public.

(B)(1) Except as provided in division (C) of this section, if the governor has a reasonable basis to believe that one or more units of a consumer product have been adulterated and that further sale or use of the consumer product presents a threat to the public health and safety, the governor may declare a public health state of emergency and make any of the following executive public health state of emergency orders:

(a) That all units of the consumer product be removed from public display by all retailers;

(b) That no units of the consumer product be sold or offered for sale during the public health state of emergency;

(c) That any retailer possessing units of the consumer product segregate these units from other merchandise and hold them or a portion of them for disposition by designated law enforcement officers or officials of the department of agriculture, the department of health, or the state board of pharmacy;

(d) Any other limitations, controls, or prohibitions that the governor considers necessary regarding the manufacture, importation, sale, or transportation of the consumer product.

(2) The governor may amend or rescind any order issued under division (B)(1) of this section.

(C) If the particular type of consumer product referred to in division (B)(1) of this section is one that falls within the jurisdiction of the department of agriculture, the department of health, or the state board of pharmacy, the governor shall not declare a public health state of emergency pursuant to that division unless requested to do so by the department or board that regulates the consumer product. If the governor grants the request, the department or board that made the request shall enforce the provisions of this section.

(D) A public health state of emergency declared under this section shall exist for not more than sixty days unless extended by the governor for an additional thirty-day period, at which time the public health state of emergency shall end unless it is extended by a concurrent resolution adopted by both houses of the general assembly. An amendment to an executive public health state of emergency order shall not be considered a new order.

(E) Any executive public health state of emergency order or amended executive public health state of emergency order issued under this section shall be disseminated promptly by means that bring the order to the attention of the general public. The governor promptly shall file the order with the secretary of state, the department of agriculture, the department of health, and the state board of pharmacy.

(F) The state is not liable for removal, or for the costs of removal, of consumer products from public display in connection with an executive public health state of emergency order issued under division (B)(1)(a) of this section. Neither the state nor an agent of the state acting pursuant to a public health state of emergency is liable for any damages or loss incurred because of any action pursuant to an executive public health state of emergency order of that type.

(G) No person shall knowingly violate an executive public health state of emergency order issued by the governor under this section. Whoever violates an executive public health state of emergency order is subject to a fine of not less than five hundred dollars. Each day a violation continues is a separate offense.

(H) The attorney general, at the direction of the governor or upon request of the director of agriculture, the director of health, the state board of pharmacy, or a prosecuting attorney may commence an action in a court of common pleas to enjoin a violation of an executive public health state of emergency order issued pursuant to this section or to compel a person to perform a duty imposed by an executive public health state of emergency order.

3715.80 Dietary Supplement Defined.

As used in sections 3715.80 to 3715.86 of the Revised Code, "dietary supplement" has the meaning given in the federal "Food, Drug, and Cosmetic Act," 108 Stat. 4327 (1994), 21 U.S.C.A. 321(ff), as amended.

3715.81 Dietary Supplement to be Treated as a Food.

For purposes of this chapter, a dietary supplement shall be treated as a food. The director of agriculture shall administer and enforce sections 3715.80 to 3715.86 of the Revised Code and any rules adopted under those sections in accordance with Chapter 3717. of the Revised Code.

3715.82 Rules.

The director of agriculture may adopt rules, in accordance with Chapter 119. of the Revised Code, to administer and enforce sections 3715.80 to 3715.86 of the Revised Code. If rules are adopted, the rules shall be no more restrictive than the regulations promulgated under the federal "Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, et seq., as amended.

3715.83 When Supplement is Adulterated.

In addition to the conditions specified in section 3715.59 of the Revised Code, a dietary supplement is adulterated if it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in its labeling or, if there are no recommended or suggested conditions of use, under the ordinary conditions of use.

If the director of agriculture finds or has cause to believe that a dietary supplement is adulterated under this section, the director shall proceed under the provisions of this chapter applicable to adulterated food. In any action taken under this section, the burden of proof shall be on the director.

3715.84 When Supplement is Not Misbranded; Status as Drug.

(A) A dietary supplement is not misbranded under section 3715.60 of the Revised Code solely because the

label or labeling contains a statement that characterizes the relationship of a nutrient or dietary ingredient to a disease or health-related condition if all of the following conditions are met:

- (1) The statement does one of the following:
 - (a) Claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of the disease in the United States;
 - (b) Describes the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body;
 - (c) Characterizes a documented mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function of the human body;
 - (d) Describes general well-being from consumption of a nutrient or dietary ingredient.
 - (2) The manufacturer of the dietary supplement has substantiation that the statement is not false or misleading.
 - (3) The label contains, prominently displayed and in boldface type, one of the following statements:
 - (a) In the case of a product manufactured or sold in Ohio and in other states, "This statement has not been evaluated by the United States food and drug administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
 - (b) In the case of a product manufactured and sold only within the state of Ohio, "This statement has not been evaluated by the Ohio department of agriculture. This product is not intended to diagnose, treat, cure, or prevent any disease."
 - (4) The manufacturer of the dietary supplement complies with the requirements of the federal "Food, Drug, and Cosmetic Act," 108 Stat. 4327 (1994), 21 U.S.C.A. 343(r)(6), as amended.
- (B) The statement described in division (A)(1) of this section shall not claim that the supplement is to be used to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.
- (C) If the director of agriculture finds or has cause to believe that a dietary supplement is misbranded under this section, the director shall proceed under the provisions of this chapter applicable to misbranded food. In any action taken under this section, the burden of proof to establish misbranding is on the director.
- (D) A dietary supplement is not a drug within the meaning of section 3715.01 or 4729.01 of the Revised Code solely because the label or labeling contains a statement authorized by this section or because a warning appears on the supplement's label.

3715.85 Publication Used in Connection with Sale of Supplement to Consumers.

- (A) As used in this section, "publication" includes a book chapter, article, or official abstract of a peer-reviewed scientific article prepared by the article's author or the editors of the publication in which the article is published.

(B) A publication used in connection with a sale to consumers of a dietary supplement is not considered part of the label of the dietary supplement if the publication meets all of the following criteria:

(1) The publication is reprinted in its entirety.

(2) The publication is not false or misleading.

(3) The publication does not promote a particular manufacturer or brand of dietary supplement.

(4) The publication is displayed or presented, alone or with other publications on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement.

(5) If the publication is displayed in a location where dietary supplements are offered for sale, the publication is physically separate from the dietary supplements.

(6) The publication does not have any other information affixed to it.

(C) Division (B) of this section does not apply to or restrict the actions of a person who offers dietary supplements for sale at retail or wholesale in the sale of books or publications as part of the person's business.

(D) If the director of agriculture finds or has cause to believe that a publication under division (B) of this section is a label and that label is false or misleading under division (B) of this section, the director shall proceed under the provisions of this chapter applicable to misbranded food. In any action taken under this section, the burden of proof to establish misbranding shall be on the director.

3715.86 Supplement is not Food Additive.

A dietary supplement is not considered a "food additive" within the meaning given in the federal "Food, Drug, and Cosmetic Act," 21 U.S.C.A. 321(s), as amended.

3715.99 Penalties.

(A) Whoever violates sections 3715.13 to 3715.19, or 3715.38 of the Revised Code is guilty of a minor misdemeanor.

(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.

(C) Whoever violates section 3715.23 or 3715.36 of the Revised Code is guilty of a misdemeanor of the second degree.

(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.

(E) Whoever violates section 3715.521 [3715.52.1] 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 consumer. Each day of violation is a separate offense.