

PHARMACY BOARD LAWS  
AS OF THE 2019 LEGISLATIVE SESSION

TITLE 50, CHAPTER 31  
MONTANA FOOD, DRUG, AND  
COSMETIC ACT

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## CHAPTER 31 MONTANA FOOD, DRUG, AND COSMETIC ACT

### Chapter Cross-References

Control of food and other commodities during emergency, 10-3-505.  
Warranty provisions under Uniform Commercial Code, 30-2-312 through 30-2-318.  
Weights, measures, standards, and labeling, Title 30, ch. 12.  
Unfair trade practices and consumer protection, Title 30, ch. 14.  
Regulation of standards and sale of grain, seed, commercial feeds, and fertilizer — regulation of produce — inspection, grading, and packing of apples, Title 80, ch. 3 through 5, 9, 10.  
Montana quality labels — regulation of poultry, eggs, and egg dealers — regulation of manufactured dairy products, Title 81, ch. 8, 20, 22.

### Chapter Administrative Rules

ARM 37.5.117 Certain Title 50 programs — applicable hearing procedures.

### Chapter Law Review Articles

A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?, O'Reilly, 58 Food & Drug L.J. 287 (2003).  
Fundamentals of Law and Regulation: An In-Depth Look at Foods, Veterinary Medicines, and Cosmetics, Page, 53 Food & Drug L.J. 777 (1998).  
Liberating Commercial Speech: Product Labeling Controls and the First Amendment, Noah & Noah, 47 Fl. L. Rev. 63 (1995).

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## Part 1 General Provisions

### Part Administrative Rules

ARM 37.110.101 Food standards.

### Part Law Review Articles

A Framework for Analysis of Products Liability in Montana, Tobias & Rossbach, 38 Mont. L. Rev. 221 (1977).

**50-31-101. Short title.** This chapter may be cited as the "Montana Food, Drug, and Cosmetic Act".  
**History:** En. Sec. 1, Ch. 307, L. 1967; R.C.M. 1947, 27-701.

**50-31-102. Applicability of chapter.** The provisions of this chapter regarding the selling of food, drugs, devices, or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of these articles for sale; the sale, dispensing, and giving of these articles; and the supplying or applying of these articles in the conduct of a food, drug, or cosmetic establishment.

**History:** En. Sec. 2, Ch. 307, L. 1967; amd. Sec. 1, Ch. 171, L. 1971; amd. Sec. 1, Ch. 114, L. 1974; amd. Sec. 3, Ch. 349, L. 1974; R.C.M. 1947, 27-702(q).

**50-31-103. Definitions.** Unless the context requires otherwise, in this chapter, the following definitions apply:

(1) "Advertisement" means 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.

(2) "Beef patty mix" means "hamburger" or "ground beef" to which have been added binders or extenders as those terms are understood by general custom and usage in the food industry.

(3) "Bottled water" means water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients, except that bottled water may optionally contain safe and suitable antimicrobial agents.

(4) "Cell-cultured edible product" means the concept of meat, including but not limited to muscle cells, fat cells, connective tissue, blood, and other components produced via cell culture, rather than from a whole slaughtered animal. A cell-cultured edible product derived from meat muscle cells, fat cells, connective tissue, blood, or other meat components must contain labeling indicating it is derived from those cells, tissues, blood, or components.

(5) "Color" includes black, white, and intermediate grays.

(6) (a) "Color additive" means a material that:

(i) is a dye, pigment, or other substance made by a process of synthesis or similar artifice or that is extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; or

(ii) when added or applied to a food, drug, or cosmetic or to the human body is capable (alone or through reaction with another substance) of imparting color to the human body.

(b) The term does not include material that has been or is exempted under the federal act.

(7) (a) "Consumer commodity", except as otherwise specifically provided by this subsection, means any food, drug, device, or cosmetic as those terms are defined by this chapter or by the federal act and regulations pursuant to the federal act.

(b) The term does not include:

(i) any tobacco or tobacco product;

(ii) a commodity subject to packaging or labeling requirements imposed under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136, et seq.) or the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21 U.S.C. 151 through 157), commonly known as the Virus-Serum-Toxin Act;

(iii) a drug subject to 50-31-306(1)(m) or 50-31-307(2)(c) or section 503(b)(1) or 506 of the federal act (21 U.S.C. 353(b)(1) and 356);

(iv) a beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C. 201, et seq.); or

(v) a commodity subject to the Federal Seed Act (7 U.S.C. 1551 through 1610).

(8) "Contaminated with filth" applies to a food, drug, device, or cosmetic not securely protected from dust, dirt, and, as far as may be necessary by all reasonable means, foreign, or injurious contaminations.

(9) (a) "Cosmetic" means:

(i) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance; and

(ii) articles intended for use as a component of these articles.

(b) The term does not include soap.

(10) "Counterfeit drug" means a drug, drug container, or drug label that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device or any likeness of an identifying mark, imprint, or device of a drug manufacturer, processor, packer, or distributor other than the person who in fact manufactured, processed, packed, or distributed the drug and that falsely purports or is represented to be the product of or to have been packed or distributed by the other drug manufacturer, processor, packer, or distributor.

(11) "Department" means the department of public health and human services provided for in 2-15-2201.

(12) "Device" (except when used in 50-31-107(2), 50-31-203(6), 50-31-306(1)(c) and (1)(q), 50-31-402(3), and 50-31-501(10)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended:

(a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or

(b) to affect the structure or function of the body of humans or other animals.

(13) "Dietary supplement" means a product, other than a tobacco product, that is intended to supplement the diet and that:

- (a) is advertised only as a food supplement;
- (b) bears or contains one or more of the following ingredients:
  - (i) a vitamin;
  - (ii) a mineral;
  - (iii) an herb or other botanical substance;
  - (iv) an amino acid;
  - (v) a dietary substance used to supplement the diet by increasing the total dietary intake or a concentrate, metabolite, constituent, extract, or combination of any ingredients described in subsections (13)(b)(i) through (13)(b)(iv);

(c) conforms to any additional provisions for the definition of dietary supplement under 21 U.S.C. 321.

(14) "Drug" means:

(a) articles recognized in the official United States Pharmacopoeia, official National Formulary, or a supplement to either of these;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(c) articles (other than food) intended to affect the structure or function of the body of humans or other animals;

(d) articles intended for use as components of any article specified in subsection (14)(a), (14)(b), or (14)(c) but does not include devices or their components, parts, or accessories.

(15) "Federal act" means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301, et seq.).

(16) "Food" means:

(a) articles used for food or drink for humans or other animals;

(b) chewing gum;

(c) articles used for components of these articles; and

(d) dietary supplements.

(17) (a) "Food additive" means a substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food. The term includes a substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food and a source of radiation intended for this use if the substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures to be safe under the conditions of its intended use. Alternatively, for a substance used in a food prior to January 1, 1958, the determination of safety under the conditions of the substance's intended use may be through either scientific procedures or experience based on common use in food.

(b) The term does not include:

(i) a pesticide chemical in or on a raw agricultural commodity;

(ii) a pesticide chemical to the extent that the pesticide chemical is intended for use or is used in the production, storage, or transportation of a raw agricultural commodity;

(iii) a color additive;

(iv) a substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the federal act, the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 603, et seq.).

(18) "Food service establishment" means a retail food establishment defined in 50-50-102 and any facility operated by a governmental entity where food is served.

(19) "Hamburger" or "ground beef" means ground fresh or frozen beef or a combination of both fresh and frozen beef, with or without the addition of suet, to which no water, binders, or extenders are added. The term includes only products entirely derived from the edible flesh of livestock or a livestock product, as meat is defined in 81-9-217. The term does not include cell-cultured edible products. There are four grades of hamburger or ground beef:

(a) "regular hamburger" or "regular ground beef" may have:

- (i) a fat content no greater than the federal standard set forth in 9 CFR 319.15; and
- (ii) a lean content of no less than 70%;
- (b) "lean hamburger" or "lean ground beef" may have:
  - (i) a fat content no greater than 22%; and
  - (ii) a lean content of no less than 78%;
- (c) "extra lean hamburger" or "extra lean ground beef" may have:
  - (i) a fat content no greater than 16%; and
  - (ii) a lean content of no less than 84%; and
- (d) "super lean hamburger" or "super lean ground beef" may have:
  - (i) a fat content no greater than 12%; and
  - (ii) a lean content of no less than 88%.
- (20) "Honey" means the nectar and saccharine plant exudations, gathered, modified, and stored in the comb by honey bees, that are levorotatory and that contain not more than 25% of water, not more than 0.25% of ash, and not more than 8% sucrose.
- (21) "Label" means a display of written, printed, or graphic matter on the immediate container of an article. "Immediate container" does not include package liners.
- (22) "Labeling" means labels and other written, printed, or graphic matter:
  - (a) on an article or its containers or wrappers;
  - (b) accompanying the article.
- (23) "Menu" means a list presented to the patron that states the food items for sale in a food service establishment.
- (24) "New drug" means a drug, the composition of which:
  - (a) is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended, or suggested in the new drug's labeling; or
  - (b) has become recognized as a result of investigations to determine the new drug's safety and effectiveness for use under the conditions prescribed but has not, other than in the investigations, been used to a material extent or for a material time under the conditions prescribed.
- (25) "Official compendium" means the official United States Pharmacopoeia, official National Formulary, or a supplement to either of these.
- (26) (a) "Package" means a container or wrapping in which a consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers.
- (b) The term does not include:
  - (i) shipping containers or wrappings used solely for the transportation of a consumer commodity in bulk or in quantity to manufacturers, packers, or processors or to wholesale or retail distributors;
  - (ii) shipping containers or outer wrappings used by retailers to ship or deliver a commodity to retail customers if the containers and wrappings bear no printed matter pertaining to a particular commodity.
- (27) "Person" includes an individual, partnership, corporation, and association.
- (28) "Pesticide chemical" means a substance that alone, in chemical combination, or in formulation with one or more other substances is an "economic poison" under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136, et seq.), as amended, and that is used in the production, storage, or transportation of raw agricultural commodities.
- (29) "Placard" means a nonpermanent sign used to display or describe food items for sale in a food service establishment or retail meat establishment.
- (30) "Principal display panel" means that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.
- (31) "Processing" means cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, freezing, or otherwise manufacturing a food or changing the physical characteristics of a food and the enclosure of the food in a package.
- (32) "Raw agricultural commodity" has the meaning as provided in 50-50-102.
- (33) "Retail meat establishment" means a commercial establishment at which meat or meat products are displayed for sale or provision to the public, with or without charge.
- (34) "Synthetically compounded" means a product formulated by a process that chemically changes a material or substance extracted from naturally occurring plant, animal, or mineral sources, except for microbiological processes.

History: En. Sec. 2, Ch. 307, L. 1967; amd. Sec. 1, Ch. 171, L. 1971; amd. Sec. 1, Ch. 114, L. 1974; amd. Sec. 3, Ch. 349, L. 1974; R.C.M. 1947, 27-702(part); amd. Sec. 8, Ch. 37, L. 1979; amd. Sec. 1, Ch. 456, L. 1979; amd. Sec. 1, Ch. 361, L. 1981; amd. Sec. 1, Ch. 605, L. 1985; amd. Sec. 1, Ch. 169, L. 1989; amd. Sec. 4, Ch. 472, L. 1989; amd. Sec. 1, Ch. 133, L. 1991; amd. Sec. 129, Ch. 418, L. 1995; amd. Sec. 307, Ch. 546, L. 1995; amd. Sec. 210, Ch. 42, L. 1997; amd. Sec. 3, Ch. 172, L. 1999; amd. Sec. 1, Ch. 373, L. 2003; amd. Sec. 6, Ch. 239, L. 2015; amd. Sec. 1, Ch. 186, L. 2019.

### Compiler's Comments

*2019 Amendment:* Chapter 186 inserted definition of cell-cultured edible product; in definition of hamburger or ground beef inserted second sentence concerning what the term does and does not include; and made minor changes in style. Amendment effective October 1, 2019.

*2015 Amendment:* Chapter 239 in definition of food additive in (a) in third sentence inserted "the determination of safety under the conditions of the substance's intended use may be"; in definition of food service establishment substituted "retail food establishment defined in 50-50-102" for "restaurant, catering vehicle, vending machine, delicatessen, fast-food retailer, or any other place that serves food at retail to the public for consumption, either at or away from the point of service"; in definition of raw agricultural commodity substituted "has the meaning as provided in 50-50-102" for "means food in its raw or natural state, including fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing"; and made minor changes in style. Amendment effective October 1, 2015.

*2003 Amendment:* Chapter 373 deleted definition of approved source that read: "'Approved source' means water from a spring, artesian well, drilled well, municipal water supply, or other source that has been found by the department to be of a safe and sanitary quality"; deleted definition of artesian water that read: "'Artesian water' means water that is forced from below the ground toward the surface through a well by natural underground pressure"; substituted definition of bottled water for former definition that read: "'Bottled water' means carbonated, demineralized, distilled, fluoridated, mineral, purified, sparkling, or other water that is from an approved source and that is disinfected and placed in a sealed container or package for human consumption"; deleted definition of carbonated water or sparkling water that read: "'Carbonated water' or 'sparkling water' means water that contains carbon dioxide"; deleted definition of demineralized water that read: "'Demineralized water' means water that has been demineralized by distillation, deionization, reverse osmosis, or other methods and that contains not more than 10 parts per million total solids"; inserted definition of dietary supplement; deleted definition of distilled water that read: "'Distilled water' means purified water that has been vaporized and condensed"; deleted definition of drinking water that read: "'Drinking water' means water that has undergone purification, distillation, demineralization, mineralization, activated carbon or particulate filtration, fluoridation, carbonation, or other similar process or has undergone minimum treatment consisting of ozonization or an acceptable disinfection process"; deleted definition of fluoridated water that read: "'Fluoridated water' means water that contains, naturally or by addition, fluoride ions in quantities of not less than 0.7 and not more than 1.4 milligrams per liter and that complies with the food and drug administration quality standards set forth in 21 CFR 103.35"; in definition of food inserted "dietary supplements"; in definition of food service establishment after "serves food" inserted "at retail"; deleted definition of mineral water that read: "'Mineral water' means water that contains more than 500 parts per million total dissolved mineral solids"; in definition of placard after "retail" inserted "meat"; deleted definition of purified water that read: "'Purified water' means water that is produced by distillation, deionization, reverse osmosis, or other method and that meets the definition of purified water in the 20th edition of the Pharmacopoeia of the United States of America, 1980"; substituted retail meat establishment for retail establishment as defined term; deleted definition of spring water that read: "'Spring water' means water that originates in an underground formation and flows naturally, without external force or vacuum, to a natural orifice in the surface of the earth"; deleted definition of water-bottling plant that read: "'Water-bottling plant' means a facility in which bottled water is produced"; deleted definition of well water that read: "'Well water' means water that:

(a) is taken from below the ground through a piping device or similar installed device using external force or vacuum;

(b) is not modified in its mineral content; and

(c) may have undergone minimum treatment consisting of ozonization or an acceptable disinfection process"; and made minor changes in style. Amendment effective October 1, 2003.

*1999 Amendment:* Chapter 172 deleted former definition of organic food that read: "'Organic food' means food that conforms to the definition in 50-31-222"; and made minor changes in style. Amendment effective on occurrence of contingency.

*Contingent Effective Date:* Section 7(2), Ch. 172, L. 1999, provided that this section is effective upon the implementation of a state organic certification program pursuant to 80-11-601(3). On Friday, June 14, 2002, the Department of Agriculture certified the passage of the petition to begin implementation of the organic certification program as referred to in 80-11-601 and also certified that implementation of the program had begun.

*1997 Amendment:* Chapter 42 in definition of consumer commodity, in (b), inserted parenthetical reference to the Federal Insecticide, Fungicide, and Rodenticide Act and in (c) inserted parenthetical reference to the United States Code; in definition of food additive, in (b)(iv), substituted "21 U.S.C. 603, et seq." for "21 U.S.C. 71, et seq."; in definition of pesticide chemical substituted "7 U.S.C. 136, et seq." for "7 U.S.C. 135 through 135k"; and made minor changes in style. Amendment effective March 12, 1997.

*1995 Amendments:* Chapter 418 in definition of consumer commodity, in (d) after "U.S.C.", inserted "201"; in definition of Department substituted "department of public health" for "department of health and environmental sciences"; in definition of State Board substituted "board of public health" for "board of health and environmental sciences"; and made minor changes in style. Amendment effective July 1, 1995.

Chapter 546 in definition of Department substituted "department of public health and human services provided for in 2-15-2201" for "department of health and environmental sciences provided for in Title 2, chapter 15, part 21"; deleted definition of State Board that read: "'State board" or "board" means the board of health and environmental sciences provided for in 2-15-2104"; and made minor changes in style. Amendment effective July 1, 1995.

*Transition:* Section 499, Ch. 418, L. 1995, provided: "The provisions of 2-15-131 through 2-15-137 apply to [this act]."

*Saving Clause:* Section 503, Ch. 418, L. 1995, was a saving clause.

*Saving Clause:* Section 571, Ch. 546, L. 1995, was a saving clause.

*1991 Amendment:* In definition of hamburger increased from three to four the number of grades, substituted "regular hamburger" for "economy hamburger" and set lean content at no less than 70%, substituted "lean hamburger" for "regular hamburger" and set fat content at no greater than 22% and lean content at no less than 78%, decreased extra lean hamburger fat content from 18% to 16% and set lean content at no less than 84%, and inserted definition of super lean hamburger with fat content no greater than 12% and lean content no less than 88%; and made minor changes in style. Amendment effective March 20, 1991.

*1989 Amendments:* Chapter 169 inserted definitions of approved source, artesian water, bottled water, carbonated water, demineralized water, distilled water, drinking water, fluoridated water, mineral water, purified water, spring water, water-bottling plant, and well water; and made minor change in grammar.

Chapter 472 corrected internal reference in definition of consumer commodity; and made minor changes in phraseology. Amendment effective April 8, 1989.

*1985 Amendment:* Inserted (23) defining "Organic food", (29) defining "Processing", and (33) defining "Synthetically compounded". Amendment effective January 1, 1986.

*1981 Amendment:* Inserted (2) defining "Beef patty mix"; inserted "or ground beef" after "Hamburger" at the beginning of (16); deleted "and with or without the addition of seasoning, if no fat other than [sic] suet is incorporated in the hamburger, the total fat content does not exceed 20%, and" after "with or without the addition of suet" in (16); added the last sentence of (16) and (16)(a) through (16)(c) relating to grades of hamburger; deleted former (17) defining "imitation hamburger"; added "or retail establishment" at the end of (26); inserted (29) defining "retail establishment"; deleted former (30) defining "wallboard" signs; and made minor changes in grammar.

**50-31-104. Department authorized to adopt rules.** (1) The department may adopt rules for the efficient enforcement of this chapter. The department may adopt by reference the regulations adopted by the food and drug administration under the federal act and the Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.).

(2) No hearing is required for adoption by reference of those regulations adopted under the federal act and the Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.).

History: En. Sec. 21, Ch. 307, L. 1967; amd. Sec. 3, Ch. 171, L. 1971; amd. Sec. 4, Ch. 349, L. 1974; R.C.M. 1947, 27-721.

## Cross-References

Adoption and publication of rules, Title 2, ch. 4, part 3.

### **Administrative Rules**

ARM 37.110.101 Food standards.

Title 37, chapter 110, subchapter 8, ARM Drinking water and ice.

**50-31-105. Publication of information by department.** (1) The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

(2) The department may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as the department 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 department from collecting, reporting, and illustrating the results of the investigations of the department.

**History:** En. Sec. 23, Ch. 307, L. 1967; R.C.M. 1947, 27-723.

**50-31-106. Inspections and taking of samples authorized.** (1) The department or its authorized agents 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 any vehicle being used to transport or hold the foods, drugs, devices, or cosmetics in commerce, for the purpose of:

(a) inspecting the factory, warehouse, establishment, or vehicle to determine if any of the provisions of this chapter are being violated; and

(b) securing samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for the sample.

(2) The department shall make or cause to be made examinations of samples secured under the provisions of this section to determine whether or not any provision of this chapter is being violated.

**History:** En. Sec. 22, Ch. 307, L. 1967; amd. Sec. 3, Ch. 187, L. 1977; R.C.M. 1947, 27-722.

### **Cross-References**

Right of privacy, Art. II, sec. 10, Mont. Const.

Searches and seizures, Art. II, sec. 11, Mont. Const.

Refusal to allow entry or inspection prohibited, 50-31-501.

### **Law Review Articles**

The Constitutionality of Civil Inspections, 21 Mont. L. Rev. 195 (Spring 1960).

Regulatory Access to Contaminated Sites: Some New Twists to an Old Tale, Schwenke, 26 Wm. & Mary Envtl. L. & Pol'y Rev. 749 (2002).

**50-31-107. False or misleading representations.** (1) An advertisement of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(2) 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 not only representations made or suggested by statement, word, design, device, sound, or a combination of these but also the extent to which the labeling or advertisement fails to reveal facts material in the light of the representations or material with respect to consequences 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 or under conditions of use as are customary or usual.

**History:** (1)En. Sec. 20, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; Sec. 27-720, R.C.M. 1947; (2)En. Sec. 2, Ch. 307, L. 1967; amd. Sec. 1, Ch. 171, L. 1971; amd. Sec. 1, Ch. 114, L. 1974; amd. Sec. 3, Ch. 349, L. 1974; Sec. 27-702, R.C.M. 1947; R.C.M. 1947, 27-702(l), 27-720(a).

### **Cross-References**

Freedom of speech and expression, Art. II, sec. 7, Mont. Const.

Specific drug advertisements considered false, 50-31-303.



**50-31-108. Regulations concerning additives.** (1) The department, upon its own motion or upon the petition of any interested party requesting that a rule be established, whenever public health or other considerations in the state require, is authorized to adopt, amend, or repeal rules, whether or not in accordance with regulations promulgated under the federal act, prescribing tolerances for any added poisonous or deleterious substances for food additives, for pesticide chemicals in or on raw agricultural commodities, or for color additives, including but not limited to zero tolerances and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities, and prescribing the conditions under which a food additive or a color additive may be safely used and exemptions when the food additive or color additive is to be used solely for investigational or experimental purposes.

(2) A petitioner shall establish by data submitted to the department that a necessity exists for the rule and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the department to determine whether the regulation should be promulgated, the department may require additional data to be submitted and failure to comply with the request is sufficient grounds to deny the request.

(3) In adopting, amending, or repealing rules relating to the substances, the department shall consider among other relevant factors the following, which the petitioner, if any, shall furnish:

(a) the name and all pertinent information concerning the substance, including, when available:

(i) its chemical identity and composition;

(ii) a statement of the conditions of the proposed use, including directions, recommendations, and suggestions and including specimens of proposed labeling; and

(iii) all relevant data bearing on the physical or other technical effect and the quantity required to produce the effect;

(b) the probable composition of or other relevant exposure from the article and of any substance formed in or on a food, drug, or cosmetic resulting from the use of the substance;

(c) the probable consumption of the substance in the diet of humans and animals taking into account any chemically or pharmacologically related substance in the diet;

(d) safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of the substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data;

(e) the availability of any needed practicable methods of analysis for determining the identity and quantity of:

(i) the substance in or on an article;

(ii) any substance formed in or on the article because of the use of the substance; and

(iii) the pure substance and all intermediates and impurities; and

(f) facts supporting a contention that the proposed use of the substance will serve a useful

purpose.

**History:** En. Sec. 13, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-713(b); amd. Sec. 1842, Ch. 56, L. 2009.

### **Compiler's Comments**

*2009 Amendment:* Chapter 56 made section gender neutral; and made minor changes in style. Amendment effective October 1, 2009.

### **Cross-References**

Misbranding drugs or devices, 50-31-306.

### **Administrative Rules**

ARM 37.110.101 Food standards.

**50-31-109. Use of additives.** Any added poisonous or deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity, or any color additive shall, with respect to any particular use or intended use, be deemed unsafe for the purpose of application of 50-31-202(2) with respect to any food, 50-31-305(1) through (5) with respect to any drug or device, or 50-31-401(1) with respect to any cosmetic unless there is in effect a regulation pursuant to 50-31-108 limiting the quantity of such substance and the use or intended use of such substance conforms to the terms prescribed by such regulation. While such regulation relating to such substance is in effect, a food, drug, or cosmetic shall not by reason of bearing or containing such substance in accordance with the regulation be considered adulterated within the meaning of 50-31-202(1), 50-31-305(1) through (5), or 50-31-401(1).

*History: En. Sec. 13, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-713(a).*

#### **Administrative Rules**

ARM 37.110.101 Food standards.

#### **Law Review Articles**

Regulation of Food Additives Never Added: An Odd Mixture of Science and Law, Krinsky, 37 Mont. L. Rev. 198 (1976).

**50-31-110. Certain agricultural chemicals not color additives.** Subsections (5) and (6) of 50-31-103 do not apply to a pesticide chemical, soil or plant nutrient, or other agricultural chemical that affects the color of produce of the soil, whether before or after harvest, solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil.

*History: En. Sec. 2, Ch. 307, L. 1967; amd. Sec. 1, Ch. 171, L. 1971; amd. Sec. 1, Ch. 114, L. 1974; amd. Sec. 3, Ch. 349, L. 1974; R.C.M. 1947, 27-702(u)(3); amd. Sec. 3, Ch. 361, L. 1981; amd. Sec. 5, Ch. 169, L. 1989; amd. Sec. 2, Ch. 373, L. 2003; amd. Sec. 2, Ch. 186, L. 2019.*

#### **Compiler's Comments**

*2019 Amendment:* Chapter 186 at beginning substituted "Subsections (5) and (6)" for "Subsections (4) and (5)". Amendment effective October 1, 2019.

*2003 Amendment:* Chapter 373 at beginning substituted references to subsections (4) and (5) of 50-31-103 for references to subsections (7) and (8) of 50-31-103; and made minor changes in style. Amendment effective October 1, 2003.

*1989 Amendment:* At beginning substituted reference to subsections (7) and (8) of 50-31-103 for reference to subsections (3) and (4) of 50-31-103.

*1981 Amendment:* Changed references to "Subsections (2) and (3)" of 50-31-103 to "Subsections (3) and (4)".

**50-31-111. When labeling requirement complied with.** A requirement made by or under authority of this chapter that a word, statement, or other information shall appear on the label is not complied with unless the word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of the article or is easily legible through the outside container or wrapper.

*History: En. Sec. 2, Ch. 307, L. 1967; amd. Sec. 1, Ch. 171, L. 1971; amd. Sec. 1, Ch. 114, L. 1974; amd. Sec. 3, Ch. 349, L. 1974; R.C.M. 1947, 27-702(i)(part); amd. Sec. 9, Ch. 37, L. 1979.*

#### **Cross-References**

Agricultural seed labeling, Title 80, ch. 5, part 1.

#### **Administrative Rules**

ARM 37.110.101 Food standards.

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## **Part 2 Food and Bottled Water**

#### **Part Cross-References**

Municipal power to inspect foodstuffs and regulate soft drink establishments, 7-21-4201, 7-21-4202.

Control of food and other commodities during emergency, 10-3-505.  
Immunity of persons donating food for free distribution, 27-1-716.  
Supervision and regulation of milk industry, Title 81, ch. 23, parts 1 through 4.

### Part Law Review Articles

The Food Quality Protection Act of 1996: Science and Law at a Crossroads, Miller, 7 Duke Envtl. L. & Pol'y F. 393 (1997).

**50-31-201. Department authorized to adopt food standards.** (1) Whenever in the judgment of the department such action will promote honesty and fair dealing in the interest of consumers, the department shall promulgate regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity, standard of quality, and/or fill of container.

(2) In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the department shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label.

(3) The definitions and standards so promulgated shall conform so far as practicable to the definitions and standards promulgated under authority of the federal act, or the department may promulgate by reference the definitions and standards promulgated under authority of the federal act.

History: En. Sec. 9, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-709.

### Cross-References

Adoption and publication of rules, Title 2, ch. 4, part 3.

### Administrative Rules

ARM 37.110.101 Food standards.

Title 37, chapter 110, subchapter 8, ARM Drinking water and ice.

### Case Notes

*Pleading of Conformity to Federal Act:* Under former law, in an action for damages resultant from consumption of an unwholesome and deleterious article, an allegation in the answer of a dealer in foodstuffs in unbroken packages that the food sold conformed to the rules of Congress under the national pure food acts and therefore could not be considered adulterated or objectionable was a conclusion of the pleader, in the absence of a statement of facts from which it could be determined that the government would permit the sale of the article in the condition it was when sold. *Bolitho v. Safeway Stores, Inc.*, 109 M 213, 95 P2d 443 (1939).

**50-31-202. When food adulterated.** A food is considered to be adulterated if:

(1) it bears or contains any poisonous or deleterious substance that may render it injurious to health. If the poisonous or deleterious substance is not an added substance, the food may not be considered adulterated under this subsection if the quantity of the substance in that food does not ordinarily render it injurious to health.

(2) it bears or contains any added poisonous or added deleterious substance, other than one that is:

(a) a pesticide chemical in or on a raw agricultural commodity;

(b) a food additive; or

(c) a color additive that is unsafe within the meaning of 50-31-109;

(3) it is a raw agricultural commodity and it bears or contains a pesticide chemical that is unsafe within the meaning of section 408(a) of the federal act (21 U.S.C. 346a(a)), as amended;

(4) it is or it bears or contains any food additive that is unsafe within the meaning of section 409 of the federal act (21 U.S.C. 348) as amended. However, if a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under section 408 of the federal act (21 U.S.C. 346) and the raw agricultural commodity has been subjected to processing, such as canning, cooking, freezing, dehydrating, or milling, the residue of the pesticide chemical remaining in or on the processed food may, notwithstanding the provisions of 50-31-108, 50-31-109, and subsection (4) of this section, not be determined unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the

concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity.

(5) it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance or if it is otherwise unfit for food;

(6) it has been produced, prepared, packed, or held under unsanitary conditions under which it may have become contaminated with filth or under which it may have been rendered diseased, unwholesome, or injurious to health;

(7) it is the product of a diseased animal or an animal that has died otherwise than by slaughter or that has been fed upon the uncooked offal from a slaughterhouse;

(8) its container is composed in whole or in part of any poisonous or deleterious substance that may render the contents injurious to health;

(9) any valuable constituent has been in whole or in part omitted or abstracted from the food;

(10) any substance has been substituted wholly or in part for the food;

(11) damage or inferiority has been concealed in any manner;

(12) any substance has been added to the food 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;

(13) it is confectionery and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of 0.4%, harmless natural wax not in excess of 0.4%, or harmless natural gum and pectin. However, this paragraph does not apply to any confectionery by reason of its containing less than 0.5% 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.

(14) it is or bears or contains any color additive that is unsafe within the meaning of the federal act.

**History:** En. Sec. 10, Ch. 307, L. 1967; R.C.M. 1947, 27-710; amd. Sec. 211, Ch. 42, L. 1997.

### **Compiler's Comments**

*1997 Amendment:* Chapter 42 in (3) and in (4), in two places, inserted parenthetical references to the United States Code; and made minor changes in style. Amendment effective March 12, 1997.

### **Cross-References**

Deceptive business practices, 45-6-318.

Montana Pesticides Act, Title 80, ch. 8.

### **Administrative Rules**

Title 37, chapter 110, ARM Food and drug standards.

### **Case Notes**

*No Requirement That Adulterated Food Poses Danger to Human Health — Embargo Justified — Summary Judgment Proper:* The dairy filed a complaint against the state, challenging the state's embargo of the dairy's milk products following the discovery of a black substance in the milk. The dairy claimed that in order for milk to be contaminated, and thus adulterated, it must be dangerous to human health. The Supreme Court held that under the plain meaning of 50-31-509, there is no requirement that adulterated food be adulterated so as to be dangerous or fraudulent in order for it to be embargoed or detained. It is sufficient that the food is adulterated. When there was no evidence raising genuine issues of material fact concerning the scope of the embargo or the quantity and identity of the black substance, the District Court did not err when it granted summary judgment to the state on these issues. *Clover Leaf Dairy v. St.*, 285 M 380, 948 P2d 1164, 54 St. Rep. 1203 (1997).

*Abstracting of Components:* Under former law, when pellets which were used for sheep feed were manufactured from screenings from the harvest of wheat by cooking and crushing the seeds, extracting the oils therefrom, and pressing the residue into pellets, it was error to give an instruction as to abstracting of valuable components, since the oil was removed from the seeds but nothing was removed from the pellets which was the product sold. *Seaton Ranch Co. v. Mont. Vegetable Oil & Feed Co.*, 123 M 396, 217 P2d 549 (1950).

*Civil Liability:* Under former law, the Pure Food and Drug Act made the seller the insurer of the purity of food products sold by him, and guilty knowledge of its impurity was not an ingredient of the offense charged. *Bolitho v. Safeway Stores, Inc.*, 109 M 213, 95 P2d 443 (1939).

*Pleading of Adulteration:* Under former law, a charge in a complaint that defendant sold and delivered to plaintiff's husband, for immediate use in his family, including plaintiff, adulterated meat containing "diseased, infected, putrid, decomposed, poisonous acid and animal matter", sufficiently charged defendant with a violation of the Pure Food and Drug Act and with a breach of duty constituting legal negligence. Kelley v. John R. Daily Co., 56 M 63, 181 P 326 (1919).

### **Law Review Articles**

Retail Dealer's Liability for Injury Arising From Consumption of Adulterated Canned Food, Besancon, 2 Mont. L. Rev. 133 (1941).

- 50-31-203. When food misbranded.** A food is considered to be misbranded if:
- (1) its labeling is false or misleading in any particular;
  - (2) it is offered for sale under the name of another food;
  - (3) it is an imitation of another food for which a definition and standard of identity has been prescribed by regulations as provided by 50-31-201 or if it is an imitation of another food that is not subject to subsection (7) of this section, unless its label bears in type of uniform size and prominence the word imitation and, immediately after that word, the name of the food imitated;
  - (4) its container is made, formed, or filled in a manner that is misleading;
  - (5) it is in package form, unless it bears a label containing:
    - (a) 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; provided that reasonable variations must be permitted and exemptions as to small packages must be established by regulations prescribed by the department;
  - (6) any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed on the label or labeling with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
  - (7) it purports to be or is represented as a food for which a definition and standard of identity have been prescribed by regulations as provided by 50-31-201, unless:
    - (a) it conforms to that definition and standard; and
    - (b) its label bears the name of the food specified in the definition and standard and, as may be required by the regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in the food;
  - (8) it purports to be or is represented as:
    - (a) a food for which a standard of quality has been prescribed by regulations as provided by 50-31-201 and its quality falls below that standard, unless its label bears, in a manner and form that the regulations specify, a statement that it falls below that standard; or
    - (b) a food for which a standard or standards of fill of container have been prescribed by regulation as provided by 50-31-201 and it falls below the standard of fill of container applicable, unless its label bears, in a manner and form that the regulations specify, a statement that it falls below that standard;
  - (9) it is not subject to the provisions of subsection (7) unless it bears labeling clearly giving:
    - (a) the common or usual name of the food, if there is one; and
    - (b) 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. To the extent that compliance with the requirements of this subsection (9)(b) is impractical or results in deception or unfair competition, exemptions must be established by regulations promulgated by the department. The requirements of this subsection (9)(b) do not apply to food products that are packaged at the direction of purchasers at retail at the time of sale, the ingredients of which are disclosed to the purchasers by other means in accordance with regulations promulgated by the department.
  - (10) it purports to be or is represented for special dietary uses, unless its label bears information concerning its vitamin, mineral, and other dietary properties that the department determines to be and by regulations prescribes as necessary in order to fully inform purchasers as to its value for special dietary uses;

(11) it bears or contains any artificial flavoring, artificial coloring, or chemical preservative unless it bears labeling stating that fact. To the extent that compliance with the requirements of this subsection is impracticable, exemptions must be established by regulations promulgated by the department. Butter, cheese, ice cream, and frozen desserts as described in 81-22-101 are exempt from label statements for artificial flavoring and artificial coloring.

(12) it is a product intended as an ingredient of another food and when used according to the directions of the purveyor will result in the final food product being adulterated or misbranded;

(13) it is a color additive, unless its packaging and labeling are in conformity with packaging and labeling requirements applicable to that color additive prescribed under the provisions of the federal act;

(14) it is a cell-cultured edible product labeled as meat but does not meet the definition of meat in 81-9-217. A cell-cultured edible product derived from meat muscle cells, fat cells, connective tissue, blood, or other meat components is not considered to be misbranded if it is labeled in accordance with 50-31-103 to indicate it is derived from those cells, tissues, blood, or components.

**History:** En. Sec. 11, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-711; amd. Sec. 2, Ch. 605, L. 1985; amd. Sec. 212, Ch. 42, L. 1997; amd. Sec. 4, Ch. 172, L. 1999; amd. Sec. 3, Ch. 186, L. 2019.

### **Compiler's Comments**

*2019 Amendment:* Chapter 186 inserted (14) concerning branding and misbranding of cell-cultured edible products as meat. Amendment effective October 1, 2019.

*1999 Amendment:* Chapter 172 deleted former (14) that read: "(14) it is labeled "organic", "organically grown", "naturally grown", "ecologically grown", or "biologically grown" but does not conform to the definition in 50-31-222". Amendment effective on occurrence of contingency.

*Contingent Effective Date:* Section 7(2), Ch. 172, L. 1999, provided that this section is effective upon the implementation of a state organic certification program pursuant to 80-11-601(3). On Friday, June 14, 2002, the Department of Agriculture certified the passage of the petition to begin implementation of the organic certification program as referred to in 80-11-601 and also certified that implementation of the program had begun.

*1997 Amendment:* Chapter 42 in (11), in last sentence, substituted "frozen desserts as described in 81-22-101" for "frozen desserts as defined in 81-22-101"; and made minor changes in style. Amendment effective March 12, 1997.

*1985 Amendment:* Inserted (14) relating to mislabeling of food as organic. Amendment effective January 1, 1986.

### **Cross-References**

Actual and constructive fraud, 28-2-404 through 28-2-406.

Deceptive business practices, 45-6-318.

### **Administrative Rules**

ARM 37.110.101 Food standards.

### **Law Review Articles**

The States' Role in Regulating Food Labeling and Advertising: The Effect of the Nutrition Labeling and Education Act of 1990, Bradley, 49 Food & Drug L.J. 649 (1994).

**50-31-204. Labeling requirements for products in semblance of honey or containing honey.** (1) Any product sold in semblance of honey which is a blend or mixture of honey and other ingredients must be labeled in such a way that the name of the main ingredient added to the honey will be printed so that it will be as prominent and conspicuous as the word "honey". The word "imitation" may not be used in the name of a product which is in semblance of honey whether or not it contains any honey.

(2) The label for a product which is not in semblance of honey and which contains honey may include the word "honey" in the name of the product. The relative position of the word "honey" in the product name and in the list of ingredients, when required, shall be determined by its prominence as an ingredient in the product.

**History:** En. Sec. 3, Ch. 307, L. 1967; amd. Sec. 2, Ch. 171, L. 1971; amd. Sec. 2, Ch. 114, L. 1974; amd. Sec. 9, Ch. 403, L. 1977; R.C.M. 1947, 27-703(part).

### **Cross-References**

Deceptive business practices, 45-6-318.

Labeling violations penalties, 50-31-506.

Injunctive remedies, 50-31-508.

### Case Notes

#### *Civil Liability:*

Under former law, the Pure Food and Drug Act made the seller the insurer of the purity of food products sold by him, and guilty knowledge of its impurity was not an ingredient of the offense charged. *Bolitho v. Safeway Stores, Inc.*, 109 M 213, 95 P2d 443 (1939).

Under former law, liability under the Pure Food and Drug Act arose from a violation of the statute, and it was immaterial whether the foundation of an action based upon such violation was laid in negligence or warranty. *Kelley v. John R. Daily Co.*, 56 M 63, 181 P 326 (1919).

*Pleading Defendant's Duty:* Under former law, a complaint alleging that at the time of the sale of impure food by defendant to plaintiff, defendant was engaged in selling at retail, to the public generally, meat and meat products for human consumption was sufficient to bring the case within the statute and disclose the duty defendant owed to the public, including plaintiff, to see that its food products offered for sale were not adulterated within the meaning of such statute. *Kelley v. John R. Daily Co.*, 56 M 63, 181 P 326 (1919).

**50-31-205. Repealed.** Sec. 6, Ch. 373, L. 2003.

History: En. Sec. 12, Ch. 307, L. 1967; R.C.M. 1947, 27-712(a).

**50-31-206. Repealed.** Sec. 6, Ch. 373, L. 2003.

History: En. Sec. 12, Ch. 307, L. 1967; R.C.M. 1947, 27-712(c).

**50-31-207. Repealed.** Sec. 6, Ch. 373, L. 2003.

History: En. Sec. 12, Ch. 307, L. 1967; R.C.M. 1947, 27-712(b).

**50-31-208. Sale of hamburger and beef patty mix.** (1) A food service establishment or retail meat establishment may not use the terms "hamburger", "burger", or other similar term in any advertisement or menu to refer to any beef patty mix. A food service establishment or retail meat establishment selling or serving beef patty mix may refer to the product as "beef patty mix" or by any other term that accurately informs the customer of the nature of the food product being sold or served.

(2) If beef patty mix is sold or served in a food service establishment or retail meat establishment, a list of ingredients must appear on the menu or label or, if there is not a menu or label, on a placard as follows:

(a) The term "beef patty mix" or any other term that accurately informs the customer of the nature of the food product and its ingredients must be included.

(b) The ingredients must be listed in descending order of predominance by weight.

(c) The lettering on the placard must be at least 1 inch in height (72-point letters), in boldface, and in colors that contrast with the placard.

(d) The placard must be posted in a permanent place, conspicuous to the customer, in each room or area where food is served or sold at retail.

(3) If hamburger or ground beef is sold in a retail meat establishment, the grade of hamburger or ground beef, as enumerated in 50-31-103(19), and the maximum fat and minimum lean content must appear on each displayed package or, if the product is not packaged for display, on a placard. If a placard is used, it must satisfy the requirements of subsections (2)(c) and (2)(d). The provisions of this subsection do not apply to the service of prepared hamburger or ground beef at a food service establishment.

History: En. Sec. 5, Ch. 456, L. 1979; amd. Sec. 2, Ch. 361, L. 1981; amd. Sec. 6, Ch. 169, L. 1989; amd. Sec. 2, Ch. 133, L. 1991; amd. Sec. 3, Ch. 373, L. 2003; amd. Sec. 4, Ch. 186, L. 2019.

### Compiler's Comments

*2019 Amendment:* Chapter 186 in (3) in first sentence substituted "50-31-103(19)" for "50-31-103(18)". Amendment effective October 1, 2019.

*2003 Amendment:* Chapter 373 throughout section after "retail" inserted "meat"; at beginning of (1)(c) deleted "If there is no menu or label"; in (3) in first sentence after "grade" inserted "of hamburger or

ground beef" and substituted "enumerated in 50-31-103(18)" for "defined in "50-31-103(24)"; and made minor changes in style. Amendment effective October 1, 2003.

*1991 Amendment:* In (3), near beginning after "maximum fat", inserted "and minimum lean". Amendment effective March 20, 1991.

*1989 Amendment:* Near beginning of (3) changed "50-31-103(16)" to "50-31-103(24)".

*1981 Amendment:* Inserted "or retail establishment" after "food service establishment" throughout (1) and (2); substituted "beef patty mix" for "imitation hamburger" throughout (1) and (2); inserted "or label" after "menu" throughout (2); deleted "wallboard or" before "placard" in (2)(c) and (2)(d); added "or sold at retail" at the end of (2)(d); added (3) requiring that grade and fat content be displayed.

#### **Cross-References**

Penalties for violation, 50-31-506.

Injunctive remedies, 50-31-508.

#### **50-31-209 through 50-31-220 reserved.**

**50-31-221. Repealed.** Secs. 5, 7(2), Ch. 172, L. 1999.

History: En. Sec. 3, Ch. 605, L. 1985.

**50-31-222. Repealed.** Secs. 5, 7(2), Ch. 172, L. 1999.

History: En. Sec. 4, Ch. 605, L. 1985.

**50-31-223. Repealed.** Secs. 5, 7(2), Ch. 172, L. 1999.

History: En. Sec. 5, Ch. 605, L. 1985.

#### **50-31-224 through 50-31-230 reserved.**

**50-31-231. Repealed.** Secs. 5, 7(2), Ch. 172, L. 1999.

History: En. Sec. 6, Ch. 605, L. 1985.

#### **50-31-232 through 50-31-235 reserved.**

**50-31-236. Repealed.** Sec. 6, Ch. 373, L. 2003.

History: En. Sec. 2, Ch. 169, L. 1989.

**50-31-237. Health claims for bottled water.** Claims of medicinal or health-giving properties on labels or in advertisements for bottled water are prohibited.

History: En. Sec. 3, Ch. 169, L. 1989.

**50-31-238. Repealed.** Sec. 6, Ch. 373, L. 2003.

History: En. Sec. 4, Ch. 169, L. 1989.

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## **Part 3 Drugs and Devices**

#### **Part Cross-References**

Pharmacy regulation, Title 37, ch. 7.

Dangerous drugs, Title 45, ch. 9.



Model Drug Paraphernalia Act, Title 45, ch. 10, part 1.  
Controlled substances, Title 50, ch. 32.

### Part Law Review Articles

A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims, Kessler & Vladeck, 96 Geo. L.J. 461 (2008).

Demanding Individually Safe Drugs Today: Overcoming the Cross-Labeling Legal Hurdle to Pharmacogenomics, Sasjack, 34 Am. J.L. & Med. 7 (2008).

State Regulation of Pharmaceutical Clinical Trials, Gibbs, 59 Food & Drug L.J. 265 (2004).

Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Standards, Geiger & Rosen, 45 DePaul L. Rev. 395 (1996).

The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling (Tort Reform and American Society: A Dialogue), Walsh, Rowland, & Dorfman, 48 Rutgers L. Rev. 821 (1996).

### 50-31-301. Definitions.

As used in this part, the following definitions apply:

(1) "Antibiotic drug" means any drug intended for use by humans containing any quantity of any chemical substance that is produced by a microorganism and that has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of such a substance).

(2) "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, marks or monograms unique to the manufacturer or distributor of the drug, or both.

(3) "Distributor" means a person who distributes for resale a drug in solid dosage form under the person's own label whether or not the person is the manufacturer of the drug.

(4) "Established name", with respect to a drug or ingredient of the drug, means:

(a) the applicable official name designated pursuant to section 508 of the federal act (21 U.S.C. 358);

(b) if there is no official name and the drug or the ingredient is an article recognized in an official compendium, then the official title of the drug or ingredient in the compendium. If this subsection (4)(b) applies to an article recognized in the United States Pharmacopoeia, the official title used in the United States Pharmacopoeia applies.

(c) if neither subsection (4)(a) nor (4)(b) applies, then the common or usual name, if any, of the drug or of the ingredient.

(5) "Legend drug" means any drug defined by section 503(b) of the federal act (21 U.S.C. 353(b)), as amended on January 15, 1980, under which its label is required to bear the statement: "Caution: Federal law prohibits dispensing without prescription."

(6) "Manufacturer" means a person who mixed the final ingredients and prepared the final drug product.

(7) "Solid dosage form" means capsules or tablets intended for oral use.

**History:** En. Sec. 15, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-715(part); amd. Sec. 1, Ch. 403, L. 1979; amd. Sec. 1, Ch. 95, L. 1981; amd. Sec. 1, Ch. 239, L. 1983; amd. Sec. 213, Ch. 42, L. 1997.

### Compiler's Comments

*1997 Amendment:* Chapter 42 in definitions of established name and legend drug inserted parenthetical references to the United States Code; in definition of legend drug substituted "federal act" for "federal Food, Drug, and Cosmetic Act"; and made minor changes in style. Amendment effective March 12, 1997.

*1983 Amendment:* In (1)(b), after "Pharmacopoeia" deleted "under different official titles".

*1981 Amendment:* Deleted "and in the Homeopathic Pharmacopoeia" after "in the United States Pharmacopoeia" in (1)(b); deleted "unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply" at the end of (1)(b); added (4) through (7) defining "code imprint", "distributor", "solid dosage form", and "legend drug".

**50-31-302. Antiseptics considered to be germicides.** The representation of a drug in its labeling or advertisement as an antiseptic is considered to be 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 which involves prolonged contact with the body.

**History:** En. Sec. 2, Ch. 307, L. 1967; amd. Sec. 1, Ch. 171, L. 1971; amd. Sec. 1, Ch. 114, L. 1974; amd. Sec. 3, Ch. 349, L. 1974; R.C.M. 1947, 27-702(n).

**50-31-303. Certain drug advertisements considered false.** (1) For the purpose of this chapter, 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, smallpox, tuberculosis, tumors, typhoid, uremia, or a sexually transmitted disease shall also be deemed to be false, except that no advertisement not in violation of 50-31-107(1) shall be deemed to be false under this section if it is disseminated only to members of the medical, dental, or veterinary professions or appears only in the scientific periodicals of these professions or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices.

(2) Whenever the department determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the department shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may deem necessary in the interests of public health.

(3) This section shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

**History:** En. Sec. 20, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-720(b); amd. Sec. 10, Ch. 37, L. 1979; amd. Sec. 17, Ch. 440, L. 1989.

#### **Compiler's Comments**

*1989 Amendment:* In (1) substituted "a sexually transmitted" for "venereal".

*Saving Clause:* Section 21, Ch. 440, L. 1989, was a saving clause.

*Severability:* Section 22, Ch. 440, L. 1989, was a severability clause.

#### **Cross-References**

Advertising drug paraphernalia prohibited, 45-10-106.

**50-31-304. Certain drugs and devices exempt from labeling requirements of chapter.** Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of this chapter, provided that such drugs and devices are being delivered, manufactured, processed, labeled, repacked, or otherwise held in compliance with regulations issued by the department or under the federal act.

**History:** En. Sec. 15, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-715(part).

#### **Cross-References**

Adoption and publication of rules, Title 2, ch. 4, part 3.

**50-31-305. When drug or device adulterated.** A drug or device shall be deemed to be adulterated if it:

(1) consists in whole or in part of any filthy, putrid, or decomposed substance;

(2) has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth or rendered injurious to health;

(3) is a drug and the methods used in or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as

to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess;

(4) is a drug and its container is composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health;

(5) is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act or it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of the federal act;

(6) purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from or its quality or purity falls below the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium or, in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality, or purity therefor set forth in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label.

(7) is not subject to the provisions of subsection (6) of this section and its strength differs from or its purity or quality falls below that which it purports or is represented to possess; or

(8) is a drug and any substance has been:

(a) mixed or packed therewith so as to reduce its quality or strength; or

(b) substituted wholly or in part therefor.

**History:** En. Sec. 14, Ch. 307, L. 1967; R.C.M. 1947, 27-714; amd. Sec. 11, Ch. 37, L. 1979.

#### **Cross-References**

Use of additives, 50-31-109.

**50-31-306. When drug or device misbranded.** (1) A drug or device is considered to be misbranded:

(a) if its labeling is false or misleading in any particular;

(b) if in package form unless it bears a label containing:

(i) the name and place of business of the manufacturer, packer, or distributor, except that a prescription drug must contain the name and place of business of the manufacturer as well as the packer or distributor; and

(ii) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided that reasonable variation may be permitted and exemptions as to small packages may be allowed in accordance with regulations prescribed by the department or issued under the federal act;

(c) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed on the label or labeling with conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(d) if it is for use by humans and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, Salvia divinorum, sulfonmethane, synthetic cannabinoids, or any chemical derivative of the substance that, after investigation, has been found to be and designated as habit-forming by regulations issued by the department under this chapter or by regulations issued pursuant to section 502(d) of the federal act (21 U.S.C. 352(d)), unless its label bears the name and quantity or proportion of the substance or derivative in juxtaposition to the statement "Warning—May be habit-forming";

(e) if it is a drug, unless its label bears to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula):

(i) the established name (as defined in 50-31-301) of the drug, if there is one; and

(ii) in case the drug is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or

preparation of any such substances contained in the drug. However, the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subsection (1)(e)(ii), applies only to prescription drugs, and to the extent that compliance with the requirements of this subsection (1)(e)(ii) is impracticable, exemptions may be allowed under regulations promulgated by the department or under the federal act.

(f) unless its labeling bears:

(i) adequate directions for use; however, if any requirement of this subsection (1)(f)(i), as applied to any drug or device, is not necessary for the protection of the public health, the department shall promulgate regulations exempting the drug or device from the requirements, and articles exempted under regulations issued under section 502(f) of the federal act (21 U.S.C. 352(f)) may also be exempt; and

(ii) adequate warnings against use in those pathological conditions or by children when its use may be dangerous to health or adequate warnings against unsafe dosage or methods or duration of administration or application, in a manner and form that are necessary for the protection of users;

(g) if it purports to be a drug, the name of which is recognized in an official compendium unless it is packaged and labeled as prescribed in the compendium. The method of packing may be modified with the consent of the department or if consent is obtained under the federal act. In the event of inconsistency between the requirements of this subsection (1)(g) and those of subsection (1)(e) as to the name by which the drug or its ingredients must be designated, the requirements of subsection (1)(e) prevail.

(h) if it has been found by the department or under the federal act to be a drug liable to deterioration, unless it is packaged in a form and manner and its label bears a statement of precautions that the regulations issued by the department or under the federal act require as necessary for the protection of public health. A regulation may not be established for any drug recognized in an official compendium until the department has informed the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements and the body has failed within a reasonable time to prescribe the requirements.

(i) if it is a drug and its container is made, formed, or filled in a way that is misleading;

(j) if it is an imitation of another drug;

(k) if it is offered for sale under the name of another drug;

(l) if it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling;

(m) if it is, purports to be, or is represented as a drug composed wholly or partly of insulin, unless:

(i) it is from a batch with respect to which a certificate or release has been issued pursuant to section 506 of the federal act (21 U.S.C. 356); and

(ii) the certificate or release is in effect with respect to the drug;

(n) if it is, purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, any other antibiotic drug, or any derivative thereof unless:

(i) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the federal act (21 U.S.C. 357); and

(ii) the certificate or release is in effect with respect to the drug. This subsection (1)(n) does not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the federal act (21 U.S.C. 357(c) or (d)).

(o) if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to the color additive prescribed under the provisions of 50-31-108 or of the federal act;

(p) in the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor of the drug includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of:

(i) the established name, as defined in 50-31-301;

(ii) the formula showing quantitatively each ingredient of the drug to the extent required for labels under section 502(e) of the federal act (21 U.S.C. 352(e)); and

(iii) other information in brief summary relating to side effects, contraindications, and effectiveness that is required in regulations issued under the federal act; or

(q) if a trademark, trade name, or other identifying mark, imprint, or device or another or any likeness of the foregoing has been placed on the drug or upon its container with intent to defraud.

(2) A drug that is subject to 50-31-307 is considered to be misbranded if, at any time prior to dispensing, its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which 50-31-307 does not apply is considered to be misbranded if, at any time prior to dispensing, its label bears the caution statement quoted in the preceding sentence.

**History:** En. Secs. 15, 16, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-715(part), 27-716(d); amd. Sec. 12, Ch. 37, L. 1979; amd. Sec. 2, Ch. 403, L. 1979; amd. Sec. 214, Ch. 42, L. 1997; amd. Sec. 5, Ch. 156, L. 2011.

### Compiler's Comments

*2011 Amendment:* Chapter 156 in (1)(d) inserted "Salvia divinorum" and "synthetic cannabinoids". Amendment effective April 8, 2011.

*1997 Amendment:* Chapter 42 in (1)(d), (1)(f)(i), (1)(m)(i), (1)(n)(i), (1)(n)(ii), and (1)(p)(ii) inserted parenthetical references to the United States Code; and made minor changes in style. Amendment effective March 12, 1997.

### Cross-References

Regulation of sale of drugs and medicines by Board of Pharmacy, 37-7-201.

**50-31-307. Dispensing of prescription drugs.** (1) A drug intended for use by humans that is included in one of the categories in subsection (2) may be dispensed only if a practitioner licensed by law to administer or prescribe the drug:

(a) provides a written prescription;  
(b) transmits the prescription directly to the pharmacy by electronic means;  
(c) provides an oral prescription that is reduced promptly to writing and filed by the pharmacist; or  
(d) authorizes the refilling of a written, electronic, or oral prescription either in the original prescription or by an oral order that is reduced promptly to writing and filed by the pharmacist.

(2) A drug must be dispensed as provided in subsection (1) if the drug:

(a) is a habit-forming drug to which 50-31-306(1)(d) applies;  
(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer or prescribe the drug; or  
(c) is limited by an approved application under section 505 of the federal act (21 U.S.C. 355) or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer or prescribe the drug.

(3) If the drug is a factory prepackaged contraceptive, other than mifepristone, it may be dispensed as provided in subsection (1) or by a registered nurse employed by a family planning clinic under contract with the department of public health and human services pursuant to a physician's written protocol specifying the circumstances under which dispensing is appropriate and pursuant to the board of pharmacy's rules concerning labeling, storage, and recordkeeping of drugs.

(4) The act of dispensing a drug contrary to the provisions of this section is considered an act that results in a drug being misbranded while held for sale.

**History:** En. Sec. 16, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-716(a); amd. Sec. 3, Ch. 472, L. 1989; amd. Sec. 130, Ch. 418, L. 1995; amd. Sec. 308, Ch. 546, L. 1995; amd. Sec. 215, Ch. 42, L. 1997; amd. Sec. 3, Ch. 125, L. 2007; amd. Sec. 1, Ch. 206, L. 2015.

### Compiler's Comments

*2015 Amendment:* Chapter 206 in (1) inserted "if a practitioner licensed by law to administer or prescribe the drug"; in (1)(a) substituted "provides a written prescription" for "upon a written prescription of a practitioner licensed by law to administer the drug"; inserted (1)(b) regarding electronic transmission of prescription; in (1)(c) substituted "provides an oral prescription" for "upon an oral prescription of the practitioner"; in (1)(d) substituted "authorizes the refilling of a written, electronic, or oral prescription" for "refilling a written or oral prescription if the refilling is authorized by the practitioner"; in (2)(b) and (2)(c) after "administer" inserted "or prescribe"; and made minor changes in style. Amendment effective April 8, 2015.

*2007 Amendment:* Chapter 125 in (3) near beginning substituted "contraceptive, other than mifepristone" for "oral contraceptive". Amendment effective October 1, 2007.

*1997 Amendment:* Chapter 42 in (2)(c) inserted parenthetical reference to the United States Code. Amendment effective March 12, 1997.

*1995 Amendments:* Chapter 418 in (3) substituted "department of public health" for "department of health and environmental sciences"; and made minor changes in style. Amendment effective July 1, 1995.

Chapter 546 in (3) substituted "department of public health and human services" for "department of health and environmental sciences". Amendment effective July 1, 1995.

*Transition:* Section 499, Ch. 418, L. 1995, provided: "The provisions of 2-15-131 through 2-15-137 apply to [this act]."

*Saving Clause:* Section 503, Ch. 418, L. 1995, was a saving clause.

Section 571, Ch. 546, L. 1995, was a saving clause.

*1989 Amendment:* At end of introductory clause of (1) substituted "that falls in one of the categories in subsection (2) may be dispensed only" for "which"; deleted former (1)(a), (1)(b), and part of (1)(c) that read: "(a) is a habit-forming drug to which 50-31-306(1)(d) applies;

(b) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(c) is limited by an approved application under section 505 of the federal act or 50-31-311 to use under the professional supervision of a practitioner licensed by law to administer such drug shall be dispensed only"; inserted (2) specifying what drugs must be dispensed according to subsection (1); inserted (3) allowing dispensing of oral contraceptives under certain circumstances; and made minor changes in phraseology and form. Amendment effective April 8, 1989.

### **Cross-References**

Regulation of sale of drugs and medicines by Board of Pharmacy, 37-7-201.

Distribution or sale of DMSO for human use, 50-42-102.

### **Case Notes**

*Duty to Warn:* The duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given to the physician who prescribes it. *Hill v. Squibb & Sons*, 181 M 199, 592 P2d 1383 (1979).

*Expert Testimony Required:* A plaintiff must produce expert testimony to sustain an action against a drug company for failure to warn adequately of side effects of its products. *Hill v. Squibb & Sons*, 181 M 199, 592 P2d 1383 (1979).

**50-31-308. Prescription drugs exempt from certain provisions of chapter.** (1) Any drug dispensed by filling or refilling a written, electronic, or oral prescription of a practitioner licensed by law to administer or prescribe the drug is exempt from the requirements of 50-31-306, except subsections (1)(a), (1)(j), (1)(k), (1)(m), (1)(n), and the packaging requirements of subsections (1)(g) and (1)(h), if the drug bears a label containing:

(a) the name and address of the dispenser;

(b) the serial number and date of the prescription or the date it was filled;

(c) the name of the prescriber; and

(d) if stated in the prescription, the name of the patient and the directions for use and cautionary statements, if any, contained in the prescription.

(2) This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to a drug dispensed in violation of 50-31-307.

**History:** En. Sec. 16, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-716(b); amd. Sec. 2, Ch. 206, L. 2015.

### **Compiler's Comments**

*2015 Amendment:* Chapter 206 in (1) inserted "electronic" and after "administer" inserted "or prescribe"; and made minor changes in style. Amendment effective April 8, 2015.

**50-31-309. Removal of drugs from prescription requirement.** The department may by regulation remove drugs subject to 50-31-306(1)(d) and 50-31-311 from the requirements of 50-31-307 when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the federal act by regulations issued thereunder may also, by regulations issued by the department, be removed from the requirements of 50-31-307.

**History:** En. Sec. 16, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-716(c).

#### **Cross-References**

Adoption and publication of rules, Title 2, ch. 4, part 3.

**50-31-310. Narcotic and marijuana laws not affected.** Nothing in 50-31-306(2), 50-31-307, 50-31-308, or 50-31-309 shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs, marijuana, or synthetic cannabinoids, as defined in the applicable federal and state laws relating to narcotic drugs, marijuana, and synthetic cannabinoids.

**History:** En. Sec. 16, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-716(e); amd. Sec. 6, Ch. 156, L. 2011.

#### **Compiler's Comments**

*2011 Amendment:* Chapter 156 inserted synthetic cannabinoids as an additional classification of drugs; and made minor changes in style. Amendment effective April 8, 2011.

#### **Cross-References**

Offenses involving dangerous drugs, Title 45, ch. 9.

**50-31-311. New drug application required.** (1) Except as provided in Title 50, chapter 42, a person may not sell, deliver, offer for sale, hold for sale, or give away any new drug unless:

(a) an application with respect to the drug has been approved and the approval has not been withdrawn under section 505 of the federal act (21 U.S.C. 355); or

(b) when not subject to the federal act, the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling of the drug and, prior to selling or offering for sale the drug, there has been filed with the department an application setting forth:

(i) full reports of investigations that have been made to show whether or not the drug is safe for use and whether the drug is effective in use;

(ii) a full list of the articles used as components of the drug;

(iii) a full statement of the composition of the drug;

(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;

(v) samples of the drug and of the articles used as components of the drug that the department may require; and

(vi) specimens of the labeling proposed to be used for the drug.

(2) An application provided for in subsection (1)(b) becomes effective on the 180th day after the filing of the application. However, if the department finds, after due notice to the applicant and giving the applicant an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling of the drug, the department shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(3) An order refusing to permit an application under this section to become effective may be revoked by the department.

**History:** En. Sec. 17, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-717(a) thru (c); amd. Sec. 1, Ch. 333, L. 1981; amd. Sec. 216, Ch. 42, L. 1997.

#### **Compiler's Comments**

*1997 Amendment:* Chapter 42 in (1)(a) inserted parenthetical reference to the United States Code; and made minor changes in style. Amendment effective March 12, 1997.

*1981 Amendment:* Inserted "Except as provided in Title 50, chapter 42" at the beginning of (1); substituted "may" for "shall" in the first sentence of (1).

**50-31-312. Exemptions from new drug application requirement.** (1) Section 50-31-311 does not apply to:

(a) a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug is plainly labeled in compliance with regulations issued by the department or pursuant to section 505(i) or 507(d) of the federal act (21 U.S.C. 355(i) or 357(d));

(b) a drug sold in this state at any time prior to the enactment of this chapter or introduced into interstate commerce at any time prior to the enactment of the federal act;

(c) any drug that is manufactured by an establishment licensed under 42 U.S.C. 262; or

(d) any drug that is subject to 50-31-306(1)(n).

(2) The provisions of 50-31-103(24) do not apply to any drug, when the drug is intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to the drug, that on October 9, 1962, or on the date immediately preceding July 1, 1967:

(a) was commercially sold or used in this state or in the United States;

(b) was not a new drug as defined by 50-31-103(24) as then in force; and

(c) was not covered by an effective application under 50-31-311 or under section 505 of the federal act (21 U.S.C. 355).

*History:* En. Sec. 17, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-717(d), (e); amd. Sec. 2, Ch. 456, L. 1979; amd. Sec. 7, Ch. 169, L. 1989; amd. Sec. 217, Ch. 42, L. 1997; amd. Sec. 4, Ch. 373, L. 2003; amd. Sec. 5, Ch. 186, L. 2019.

#### **Compiler's Comments**

*2019 Amendment:* Chapter 186 in (2) in introductory clause and in (2)(b) substituted "50-31-103(24)" for "50-31-103(23)". Amendment effective October 1, 2019.

*2003 Amendment:* Chapter 373 in (2) and (2)(b) substituted "50-31-103(23)" for "50-31-103(30)". Amendment effective October 1, 2003.

*1997 Amendment:* Chapter 42 in (1)(a) and (2)(c) inserted parenthetical references to the United States Code; in (1)(c) substituted "manufactured by an establishment licensed under 42 U.S.C. 262" for "licensed under the Virus, Serum, and Toxin Act of July 1, 1902 (U.S.C. 1958 ed. Title 42, chapter 6A, sec. 262)"; and made minor changes in style. Amendment effective March 12, 1997.

*1989 Amendment:* Near beginning of (2) and in (2)(b) substituted "50-31-103(30)" for "50-31-103(21)".

**50-31-313. Code imprint required on legend drugs.** No legend drug in solid dosage form may be manufactured or distributed in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug.

*History:* En. Sec. 2, Ch. 95, L. 1981.

#### **Cross-References**

Penalty for violation, 50-31-506.

**50-31-314. Exemptions from code imprint requirement.** The board of pharmacy may grant exemptions from the requirements of 50-31-313 and 50-31-315 upon a showing by a drug manufacturer or distributor that size, physical characteristics, or other compelling reasons render application of a code imprint on a legend drug subject to the provisions of 50-31-313 impractical or impossible. Any exemption granted must be included in the list required by 50-31-315 and must describe the physical characteristics and type of drug covered by the exemption.

*History:* En. Sec. 3, Ch. 95, L. 1981; amd. Sec. 1, Ch. 247, L. 1983.

#### **Compiler's Comments**

*1983 Amendment:* Substituted "board of pharmacy" for "board of pharmacists".

#### **Cross-References**

Board of Pharmacy, Title 37, ch. 7, part 2.



**50-31-315. List of code imprints to be provided.** Upon request of the board of pharmacy, all manufacturers and distributors of legend drugs in solid dosage form who produce or distribute legend drugs in Montana must provide and keep current a list of those drugs, which list identifies the manufacturer and the specific type of each drug by code imprint.

**History:** En. Sec. 4, Ch. 95, L. 1981; amd. Sec. 1, Ch. 247, L. 1983.

**Compiler's Comments**

*1983 Amendment:* Substituted "board of pharmacy" for "board of pharmacists".

**Cross-References**

Board of Pharmacy, Title 37, ch. 7, part 2.  
Penalty for violation, 50-31-506.

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## Part 4 Cosmetics

**Part Cross-References**

Licensing of barbers, cosmetologists, electrologists, estheticians, and manicurists, Title 37, ch. 31.

**50-31-401. When cosmetic adulterated.** A cosmetic shall be deemed to be adulterated if:

(1) it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual;

(2) it consists in whole or in part of any filthy, putrid, or decomposed substance;

(3) it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or rendered injurious to health;

(4) its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(5) it is not a hair dye and it is or it bears or contains a color additive which is unsafe within the meaning of the federal act.

**History:** En. Sec. 18, Ch. 307, L. 1967; R.C.M. 1947, 27-718(part).

**Cross-References**

Use of additives, 50-31-109.

**50-31-402. When cosmetic misbranded.** A cosmetic shall be deemed to be misbranded if:

(1) its labeling is false or misleading in any particular;

(2) in package form unless it bears a label containing:

(a) the name and place of business of the manufacturer, packer, or distributor; and

(b) 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 department;

(3) any word, statement, or other information required by or under authority of this chapter 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;

(4) its container is so made, formed, or filled as to be misleading;

(5) it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of the federal act.

**History:** En. Sec. 19, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; R.C.M. 1947, 27-719(part).

**50-31-403. Exceptions for hair dyes.** (1) Section 50-31-401 shall not apply to coal tar hair dye, the label of which 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", and the labeling of which bears adequate directions for such preliminary testing.

(2) Section 50-31-402(5) shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in 50-31-404).

**History:** (1)En. Sec. 18, Ch. 307, L. 1967; Sec. 27-718, R.C.M. 1947; (2)En. Sec. 19, Ch. 307, L. 1967; amd. Sec. 107, Ch. 349, L. 1974; Sec. 27-719, R.C.M. 1947; R.C.M. 1947, 27-718(part), 27-719(part).

**50-31-404. Term hair dye not to include eyelash or eyebrow dyes.** For the purpose of 50-31-401(5) and 50-31-403, the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

**History:** En. Sec. 18, Ch. 307, L. 1967; R.C.M. 1947, 27-718(part).

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## Part 5 Prohibited Acts, Penalties, and Remedies

**50-31-501. Prohibited acts.** The following acts and the causing of the acts within the state of Montana 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 of any food, drug, device, or cosmetic for pay or otherwise;

(4) the sale, delivery for sale, holding for sale, or offering for sale of any article in violation of 50-31-311;

(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 50-31-106;

(7) the giving of a guaranty or undertaking if the guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking signed by and containing the name and address of a person residing in the state of Montana and 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 50-31-509;

(9) the alteration, mutilation, destruction, obliteration, or commission of any other act with respect to a food, drug, device, or cosmetic or the removal, in whole or in part, of the labeling of a food, drug, device, or cosmetic if the act is done while the article is held for sale and results in the article being adulterated or 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 regulations promulgated under the provisions of this chapter or federal act;

(11) using on the labeling of any drug or in any advertisement relating to the drug any representation or suggestion that an application with respect to the drug is effective under 50-31-311 or that the drug complies with the provisions of 50-31-311;

(12) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer, or distributor to maintain for transmittal or to transmit to any practitioner, licensed by applicable law to administer the drug and who makes written request for information as to the drug, true and correct copies of all printed matter that is required to be included in any package in which that drug is distributed or sold or other printed matter as is approved under the federal act. This subsection

does not exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(13) placing or causing to be placed upon any drug, device, or container of a drug or device, with intent to defraud, the trade name, other identifying mark, or imprint of another or any likeness of the name, mark, or imprint;

(14) selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container of the drug or device with knowledge that the trade name, other identifying mark, or imprint of another or any likeness of any of the foregoing has been placed on the drug, device, or container in a manner prohibited by subsection (13);

(15) making, selling, disposing of, or causing to be made, sold, or disposed of or keeping in possession, control, or custody or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce a trade name, other identifying mark, or imprint of another or any likeness of the name, mark, or imprint upon any drug, device, or container of the drug or device;

(16) the using by any person to the person's own advantage or revealing, other than to officers or employees of the department or the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of this chapter concerning any method or process that as a trade secret is entitled to protection;

(17) the distribution in commerce of a consumer commodity if the commodity is contained in a package or if there is affixed to that commodity a label that does not conform to the provisions of this chapter and of regulations promulgated under authority of this chapter. This prohibition does not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that the persons:

(a) are engaged in the packaging or labeling of the commodities; or

(b) prescribe or specify by any means the manner in which the commodities are packaged or labeled.

(18) the labeling or packaging of a food, drug, device, or cosmetic that fails to conform with the requirements of this chapter.

**History:** En. Sec. 3, Ch. 307, L. 1967; amd. Sec. 2, Ch. 171, L. 1971; amd. Sec. 2, Ch. 114, L. 1974; amd. Sec. 9, Ch. 403, L. 1977; R.C.M. 1947, 27-703(1) thru (16); amd. Sec. 309, Ch. 546, L. 1995; amd. Sec. 5, Ch. 373, L. 2003.

### **Compiler's Comments**

*2003 Amendment:* Chapter 373 in (9) after "obliteration" substituted "or commission" for "or removal of the whole or any part of the labeling of or the doing" and after "cosmetic" inserted "or the removal, in whole or in part, of the labeling of a food, drug, device, or cosmetic"; in (13) after "drug" inserted "or device"; in (18) after "drug" inserted "device"; and made minor changes in style. Amendment effective October 1, 2003.

*1995 Amendment:* Chapter 546 in (16), after "other than to", deleted "the state board"; and made minor changes in style. Amendment effective July 1, 1995.

*Saving Clause:* Section 571, Ch. 546, L. 1995, was a saving clause.

### **Cross-References**

Immunity of persons donating food for free distribution, 27-1-716.

Deceptive business practices, 45-6-318.

Alteration of dangerous drug labels unlawful — penalty, 45-9-105, 45-9-106.

Penalties, 50-31-506.

### **Case Notes**

#### *Civil Liability:*

Under former law, the Pure Food and Drug Act made the seller the insurer of the purity of food products sold by him, and guilty knowledge of its impurity was not an ingredient of the offense charged. *Bolitho v. Safeway Stores, Inc.*, 109 M 213, 95 P2d 443 (1939).

Under former law, liability under the Pure Food and Drug Act arose from a violation of the statute, and it was immaterial whether the foundation of an action based upon such violation was laid in negligence or warranty. *Kelley v. John R. Daily Co.*, 56 M 63, 181 P 326 (1919).

*Pleading Defendant's Duty:* Under former law, a complaint alleging that at the time of the sale of impure food by defendant to plaintiff, defendant was engaged in selling at retail, to the public generally, meat and meat products for human consumption was sufficient to bring the case within the statute and

disclose the duty defendant owed to the public, including plaintiff, to see that its food products offered for sale were not adulterated within the meaning of such statute. *Kelley v. John R. Daily Co.*, 56 M 63, 181 P 326 (1919).

**50-31-502. Unlawful labeling of products resembling honey.** It is unlawful for any person to sell or offer for sale any product which is in semblance of honey and which is labeled, advertised, or otherwise represented to be honey if it is not honey.

**History:** En. Sec. 3, Ch. 307, L. 1967; amd. Sec. 2, Ch. 171, L. 1971; amd. Sec. 2, Ch. 114, L. 1974; amd. Sec. 9, Ch. 403, L. 1977; R.C.M. 1947, 27-703(part).

#### **Cross-References**

Labeling requirements, 50-31-204.

Penalties, 50-31-506.

**50-31-503. Prosecution of minor violations not required.** Nothing in this chapter shall be construed as requiring the department to report for the institution of proceedings under this chapter minor violations of this chapter whenever the department believes that the public interest will be adequately served in the circumstances by a suitable written notice of warning.

**History:** En. Sec. 8, Ch. 307, L. 1967; R.C.M. 1947, 27-708.

**50-31-504. Notice and hearing required prior to prosecution.** Before a violation of this chapter is reported to a state or county attorney for the institution of a criminal proceeding, the person against whom the proceeding is contemplated must be given appropriate notice and an opportunity to present the person's views before the department or its designated agent, either orally or in writing and either in person or by attorney, with regard to the contemplated proceeding.

**History:** En. Sec. 7, Ch. 307, L. 1967; amd. Sec. 2, Ch. 187, L. 1977; R.C.M. 1947, 27-707(part); amd. Sec. 1843, Ch. 56, L. 2009.

#### **Compiler's Comments**

*2009 Amendment:* Chapter 56 made section gender neutral; and made minor changes in style. Amendment effective October 1, 2009.

#### **Cross-References**

Contested case defined — applicability of Montana Administrative Procedure Act, 2-4-102.

**50-31-505. Duty of state or county attorneys to prosecute.** Each state attorney or county attorney to whom the department reports a violation of this chapter shall cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

**History:** En. Sec. 7, Ch. 307, L. 1967; amd. Sec. 2, Ch. 187, L. 1977; R.C.M. 1947, 27-707(part).

#### **Cross-References**

Duties of Attorney General, 2-15-501.

Duties of County Attorney relating to state matters, 7-4-2716.

**50-31-506. Penalties.** (1) Any person who violates any of the provisions of 50-31-204, 50-31-208, 50-31-313, 50-31-315, 50-31-501, or 50-31-502 is guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than 3 months, a fine of not more than \$250, or both such imprisonment and fine.

(2) If the violation is committed after a conviction of such person under this section has become final, such person shall be subject to imprisonment for not more than 6 months, a fine of not more than \$500, or both such imprisonment and fine.

**History:** En. Sec. 5, Ch. 307, L. 1967; R.C.M. 1947, 27-705(a); amd. Sec. 3, Ch. 456, L. 1979; amd. Sec. 5, Ch. 95, L. 1981.

#### **Compiler's Comments**

*1981 Amendment:* Extended the penalties to violation of 50-31-313 or 50-31-315; made minor changes in grammar.

## Cross-References

Immunity of persons donating food for free distribution, 27-1-716.

Unauthorized sale or distribution of DMSO for human use, 50-42-102.

## Case Notes

*Reliance on Guaranty:* Section 27-110, R.C.M. 1947 (since repealed), was not open to the construction that the presence of a guaranty executed by the wholesaler, jobber, or manufacturer as to the purity of an article of food sold in the original, unbroken package and found adulterated was a defense to an action against the dealer for damages resulting from illness caused by eating the food and did not relieve him from civil liability under section 74-321, R.C.M. 1947 (since repealed). *Bolitho v. Safeway Stores, Inc.*, 109 M 213, 95 P2d 443 (1939).

*Knowledge of Impurity:* Under former law, the seller of food products was made insurer of their purity, and guilty knowledge on his part was not an ingredient of the offense prohibited; the obligation was personal and could not be avoided by showing that the impure food was purchased from a foreign concern and bore the stamp of approval by the government inspectors. *Kelley v. John R. Daily Co.*, 56 M 63, 181 P 326 (1919).

**50-31-507. Exceptions to penalties.** (1) A person is not subject to the penalties of 50-31-506 for having violated 50-31-501(1) or (3) if the person establishes a guaranty or undertaking signed by and containing the name and address of the person residing in the state of Montana 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 this chapter, designating this chapter.

(2) The publisher, radiobroadcast 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, is not liable under 50-31-506 by reason of the dissemination by the person of the false advertisement, unless the person has refused, on the request of the department, to furnish the department the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency residing in the state of Montana who causes the person to disseminate the advertisement.

History: En. Sec. 5, Ch. 307, L. 1967; R.C.M. 1947, 27-705(b), (c); amd. Sec. 1844, Ch. 56, L. 2009.

## Compiler's Comments

*2009 Amendment:* Chapter 56 made section gender neutral; and made minor changes in style. Amendment effective October 1, 2009.

## Cross-References

Freedom of speech and expression, Art. II, sec. 7, Mont. Const.

## Case Notes

*Reliance on Guaranty:* Section 27-110, R.C.M. 1947 (since repealed), was not open to the construction that the presence of a guaranty executed by the wholesaler, jobber, or manufacturer as to the purity of an article of food sold in the original, unbroken package and found adulterated was a defense to an action against the dealer for damages resulting from illness caused by eating the food and did not relieve him from civil liability under section 74-321, R.C.M. 1947 (since repealed). *Bolitho v. Safeway Stores, Inc.*, 109 M 213, 95 P2d 443 (1939).

*Knowledge of Impurity:* Under former law, the seller of food products was made insurer of their purity, and guilty knowledge on his part was not an ingredient of the offense prohibited; the obligation was personal and could not be avoided by showing that the impure food was purchased from a foreign concern and bore the stamp of approval by the government inspectors. *Kelley v. John R. Daily Co.*, 56 M 63, 181 P 326 (1919).

**50-31-508. Injunction to restrain prohibited acts.** In addition to the remedies hereinafter provided, the department is hereby authorized to apply to district court for and such court shall have jurisdiction upon hearing and for cause shown to grant a temporary or permanent injunction restraining any person from violating any provision of 50-31-204, 50-31-208, 50-31-501, or 50-31-502, irrespective of whether or not there exists an adequate remedy at law.

History: En. Sec. 4, Ch. 307, L. 1967; R.C.M. 1947, 27-704; amd. Sec. 4, Ch. 456, L. 1979.

## Cross-References

Injunctions, Title 27, ch. 19.

**50-31-509. Detainer of adulterated or misbranded articles.** (1) If an agent of the department finds or has probable 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 this chapter, the agent shall affix to the article a tag or other appropriate marking giving notice that the article is or is suspected of being adulterated or misbranded 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 agent or the court. It is unlawful for a person to remove or dispose of a detained or embargoed article by sale or otherwise without permission. The owner of an embargoed article or another authorized person and the department may enter into a disposal agreement providing for the disposal, reconditioning, or other disposition of the embargoed article. If an agreement is executed or if the embargo is otherwise removed by the department or the court, neither the department nor the state may be held liable for damages caused by the embargo provided that probable cause existed for its imposition.

(2) If an article detained or embargoed under subsection (1) is found by the agent to be adulterated or misbranded and a disposal agreement is not executed as provided in subsection (1), the agent shall petition the justice of the peace, city judge, or district court in whose jurisdiction the article is detained or embargoed for an order for condemnation of the article. If the agent finds that an article detained or embargoed is not adulterated or misbranded, the agent shall remove the tag or other marking.

(3) If the court finds that a detained or embargoed article is adulterated or misbranded, the article must, after entry of the decree, be destroyed at the expense of the claimant of the article under the supervision of the agent and all court costs and fees and storage and other proper expenses must be taxed against the claimant of the article or the claimant's agent.

(4) If the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after the costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the article will be labeled or processed, has been executed, may by order direct that the article be delivered to the claimant of the article for the labeling or processing under the supervision of an agent of the department. The expense of the supervision must be paid by claimant. The article must be returned to the claimant on the representation to the court by the department that the article is no longer in violation of this chapter and that the expenses of the supervision have been paid.

**History:** En. Sec. 6, Ch. 307, L. 1967; amd. Sec. 1, Ch. 187, L. 1977; R.C.M. 1947, 27-706(1) thru (3); amd. Sec. 1, Ch. 158, L. 1981; amd. Sec. 1845, Ch. 56, L. 2009.

## Compiler's Comments

*2009 Amendment:* Chapter 56 made section gender neutral; and made minor changes in style. Amendment effective October 1, 2009.

*1981 Amendment:* Added the last two sentences in (1) relating to an agreement by the owner to dispose of embargoed articles and to nonliability of the state; inserted "and a disposal agreement is not executed as provided in subsection (1), the agent" before "shall petition the justice of peace" near the beginning of (2); made minor changes in grammar.

## Cross-References

District Court jurisdiction, Title 3, ch. 5, part 3.

Justices' Courts jurisdiction, Title 3, ch. 10, part 3.

City Court jurisdiction, Title 3, ch. 11, part 1.

## Administrative Rules

Title 37, chapter 110, subchapter 2, ARM Retail food establishments.

## Case Notes

*Agency's Probable Cause Determination Reviewable by Courts — De Minimis Exception Applicable to Review:* Unlike federal law, state law provides for judicial review of an agency's probable cause determination under this section. Agency actions under this section, including an agency's probable cause determination, are reviewable by the courts, and courts are not prohibited from applying

the de minimis exception to review of the agency's probable cause determination. *Clover Leaf Dairy v. St.*, 285 M 380, 948 P2d 1164, 54 St. Rep. 1203 (1997).

*No Requirement That Adulterated Food Poses Danger to Human Health — Embargo Justified — Summary Judgment Proper:* The dairy filed a complaint against the state, challenging the state's embargo of the dairy's milk products following the discovery of a black substance in the milk. The dairy claimed that in order for milk to be contaminated, and thus adulterated, it must be dangerous to human health. The Supreme Court held that under the plain meaning of this section, there is no requirement that adulterated food be adulterated so as to be dangerous or fraudulent in order for it to be embargoed or detained. It is sufficient that the food is adulterated. When there was no evidence raising genuine issues of material fact concerning the scope of the embargo or the quantity and identity of the black substance, the District Court did not err when it granted summary judgment to the state on these issues. *Clover Leaf Dairy v. St.*, 285 M 380, 948 P2d 1164, 54 St. Rep. 1203 (1997).

*Chocolate Inventory Destroyed — Contamination Exclusion Inapplicable:* After discovering that a worker had been exposed to hepatitis, the owners of Helena's Parrot Confectionery (the Parrot) immediately alerted the city health department. When the state Department of Health and Environmental Sciences [now Department of Public Health and Human Services] subsequently placed an embargo on all candy, the Parrot, without testing for contamination, voluntarily destroyed its existing inventory and submitted a claim for the loss to its insurance company. Citing the high probability of contamination and the contamination exclusion in the insurance contract, the District Court granted summary judgment in favor of the insurance company. Adopting the contamination definitions in *Am. Cas. Co. of Reading, Pa. v. Myrick*, 304 F2d 179 (5th Cir. 1962), *Hi-G, Inc. v. St. Paul Fire & Marine Ins. Co.*, 391 F2d 924 (1st Cir. 1968), and *Auten v. Employers Nat'l Ins. Co.*, 722 SW 2d 468 (Tex. App. 1987), the Supreme Court reversed, holding that absent proof of "actual" contamination, the contamination exclusion does not bar coverage for the Parrot's losses. *Duensing v. Traveler's Co.*, 257 M 376, 849 P2d 203, 50 St. Rep. 316 (1993).

**50-31-510. Condemnation of perishables.** Whenever the department or any of its authorized agents find in any room, building, vehicle of transportation, or other structure any meat, seafood, poultry, vegetable, fruit, or other perishable article which is unsound or contains any filthy, decomposed, or putrid substance or that may be poisonous or deleterious to health or otherwise unsafe, the article being hereby declared to be a nuisance, the department or its authorized agent shall immediately condemn or destroy the article or in any other manner render the article unsalable as human food.

History: En. Sec. 6, Ch. 307, L. 1967; amd. Sec. 1, Ch. 187, L. 1977; R.C.M. 1947, 27-706(4).