HOUSE BILL NO. 401

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A BILL FOR AN ACT ENTITLED: "AN ACT PROHIBITING THE MANUFACTURE FOR SALE, SALE, HOLDING OR OFFERING FOR SALE, OR DISTRIBUTION OF CELL-CULTURED EDIBLE PRODUCT; PROVIDING PENALTIES; PROVIDING RULEMAKING AUTHORITY; PROVIDING DEFINITIONS; AND AMENDING SECTIONS ~~30-12-210,~~ 50-31-103, 50-31-203, 50-31-501, AND 81-9-217, MCA."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Cell-cultured edible product -- prohibition -- rulemaking authority -- definition.** (1) It is unlawful for a person to manufacture for sale, sell, hold or offer for sale, or distribute cell-cultured edible product in this state.

(2) The department may adopt rules to implement this section.

(3) As used in [section 2] and this section, the following definitions apply:

(a) "Cell-cultured edible product" has the same meaning as provided in 50-31-103.

(b) "Retail food establishment" has the same meaning as provided in 50-50-102.

NEW SECTION. **Section 2. Penalty -- violation -- stop sale.** (1) A person who knowingly violates

~~this part~~ [section 1] commits a misdemeanor ~~and on conviction shall be imprisoned for not more than 60 days~~ and is subject to the provisions of 50-31-506.

(2) A retail food establishment that manufactures for sale, sells, holds or offers for sale, or distributes cell-cultured edible product as defined in [section 1] is found in violation of ~~this part~~ [section 1] and is subject to disciplinary action pursuant to 50-50-107 through 50-50-109.

(3) In addition to the penalties provided in this ~~part~~ section, the license of a restaurant, store, or other business may be suspended as provided in the applicable licensing law on the conviction of an owner or employee of that business for a violation of ~~this part~~ [section 1] in connection with that business.

(4) A product found to be in violation of ~~this part~~ [section 1] is subject to the provisions of this chapter and an immediate stop sale order.

~~**Section 3.** Section 30-12-210, MCA, is amended to read:~~

~~"**30-12-210. Police powers.** In enforcing the provisions of parts 1 through 5 and [sections 1 and 2] or any other law pertaining to weights and measures, the department may, in the manner provided by law for peace officers, arrest violators, conduct searches and inspections, and seize for use as evidence incorrect or unsealed weights and measures or packages of commodities unlawfully used, possessed, offered, or exposed for sale or unlawfully sold."~~

Section 3. Section 50-31-103, MCA, is amended to read:

"**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)~~(11)) 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."

Section 4. Section 50-31-203, MCA, is amended to read:

"**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;

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~~."

Section 5. Section 50-31-501, MCA, is amended to read:

"**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 manufacture, sale or delivery, holding, or offering for sale of cell-cultured edible product pursuant to [section 1];

~~(6)~~(7) the refusal to permit entry or inspection or to permit the taking of a sample, as authorized by 50-31-106;

~~(7)~~(8) 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)~~(9) the removal or disposal of a detained or embargoed article in violation of 50-31-509;

~~(9)~~(10) 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)~~(11)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)~~(12)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)~~(13)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)~~(14)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)~~(15)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)~~ (14);

~~(15)~~(16)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)~~(17)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)~~(18)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)~~(19)the labeling or packaging of a food, drug, device, or cosmetic that fails to conform with the requirements of this chapter."

~~(l)~~(k) if it bears or contains an artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, provided that to the extent that compliance with the requirements of this subsection ~~(8)(l)~~ (8)(k) is impracticable, exemptions must be established by rules promulgated by the board; or

~~(m)~~(l) if it fails to bear directly on the meat and on its containers, as the board may by rule prescribe, the official inspection legend and establishment number of the establishment where the product was prepared and other information that the board may require to ensure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the meat in a wholesome condition.

(9) (a) "Mobile slaughter facility" means a mobile unit that is operated by a person licensed by the board to slaughter livestock or poultry, that is capable of providing onsite slaughter services for the owner of the livestock or poultry, and at which inspection of the slaughter of livestock or poultry or the preparation of meat food products is regulated under 81-9-216 through 81-9-220 and 81-9-226 through 81-9-236.

(b) The term does not mean a person engaged in custom slaughtering as provided in 81-9-218(2).

(10) "Official establishment" means an establishment licensed by the board at which inspection of the slaughter of livestock or poultry or the preparation of meat food products is maintained under 81-9-216 through 81-9-220 and 81-9-226 through 81-9-236. The term includes a mobile slaughter facility.

(11) "Pesticide chemical", "food additive", "color additive", and "raw agricultural commodity" have the same meanings as provided in 21 U.S.C. 321.

(12) "Poultry" means any domesticated bird, whether alive or dead.

(13) "Prepared" means slaughtered, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed."

NEW SECTION. **Section 7. Codification instruction.** [Sections 1 and 2] are intended to be codified as ~~a new~~ an integral part ~~in Title 30, chapter 12,~~ of Title 50, chapter 31, part 5, and the provisions of ~~Title 30, chapter 12,~~ Title 50, chapter 31, part 5, apply to [sections 1 and 2].

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