HOUSE BILL NO. 327

INTRODUCED BY A. REDFIELD

A BILL FOR AN ACT ENTITLED: "AN ACT CLARIFYING LABELING REQUIREMENTS FOR MEAT; PROVIDING A DEFINITION OF "CELL-CULTURED EDIBLE PRODUCT"; CLARIFYING THE DEFINITION OF "HAMBURGER" AND "GROUND BEEF"; CLARIFYING CIRCUMSTANCES WHEN FOOD AND MEAT IS MISBRANDED OR MISLABELED; AND AMENDING SECTIONS 50-31-103, 50-31-203, AND 81-9-217, MCA."

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

Section 1. 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) "Color" includes black, white, and intermediate grays.

(5) (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.

(6) (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).

(7) "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.

(8) (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.

(9) "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.

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

(11) "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.

(12) "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 (12)(b)(i) through (12)(b)(iv);

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

(13) "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 (13)(a), (13)(b), or (13)(c) but does not include devices or their components, parts, or accessories.

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

(15) "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.

(16) (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.).

(17) "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.

(18) "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. <u>The term includes only products derived from the edible flesh of livestock or a livestock product, as meat is defined in 81-9-217.</u> 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%.

(19) "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.

(20) "Label" means a display of written, printed, or graphic matter on the immediate container of an article. "Immediate container" does not include package liners.

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

(a) on an article or its containers or wrappers;

(b) accompanying the article.

(22) "Menu" means a list presented to the patron that states the food items for sale in a food service establishment.

(23) "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.

(24) "Official compendium" means the official United States Pharmacopoeia, official National Formulary, or a supplement to either of these.

(25) (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.

(26) "Person" includes an individual, partnership, corporation, and association.

(27) "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.

(28) "Placard" means a nonpermanent sign used to display or describe food items for sale in a food service establishment or retail meat establishment.

(29) "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.

(30) "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.

(31) "Raw agricultural commodity" has the meaning as provided in 50-50-102.

(32) "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.

(33) "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 2. 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;

(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 labeled as meat but does not meet the definition of meat in 81-9-217."

Section 3. Section 81-9-217, MCA, is amended to read:

"81-9-217. Definitions. As used in 81-9-216 through 81-9-220 and 81-9-226 through 81-9-236, the following definitions apply:

(1) "Adulterated" means the term applied to meat if:

(a) it bears or contains a poisonous or deleterious substance that may render it injurious to health, except that if the substance is not an added substance, the product may not be considered adulterated if the quantity of the substance is insufficient to ordinarily render it injurious to health;

(b) it bears or contains, by reason of administration of any substance to the meat, an added poisonous or added deleterious substance other than a color additive, a food additive, or a pesticide chemical in or on a raw agricultural commodity, any of which may in the board's judgment make the meat unfit for human food;

(c) it is in whole or in part a raw agricultural commodity and bears or contains a pesticide chemical that is unsafe as provided in the Federal Food, Drug and Cosmetic Act;

(d) it bears or contains a food additive that is unsafe as provided in the Federal Food, Drug and Cosmetic Act;

(e) it bears or contains a color additive that is unsafe as provided in the Federal Food, Drug and

Cosmetic Act; however, the meat that is not otherwise considered adulterated under subsection (1)(c), (1)(d), or (1)(e) is considered adulterated if use of the pesticide chemical, food additive, or color additive in or on the article is prohibited by rule of the board;

(f) it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

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

(h) it is in whole or in part the product of an animal, including poultry, that has died otherwise than by slaughter;

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

(j) it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to 21 U.S.C. 348; or

(k) any valuable constituent has been in whole or in part omitted or abstracted from the meat, any substance has been substituted wholly or in part for meat, damage or inferiority has been concealed in any manner, or any substance has been added to it or mixed or packed with it so as to increase its bulk or weight or make it appear better or of greater value than it is.

(2) "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.

~~(2)~~(3) "Chief" means the chief meat inspector appointed as provided in 81-9-226.

~~(3)~~(4) "Federal Food, Drug and Cosmetic Act" means 21 U.S.C. 301 through 392, as that law read on October 1, 1987.

~~(4)~~(5) "Livestock" means cattle, buffalo, sheep, swine, goats, rabbits, horses, mules or other equines, and alternative livestock, as defined in 87-4-406, whether alive or dead.

~~(5)~~(6) "Livestock product" or "poultry product" means a product capable of use as human food that is wholly or partially made from meat and is not specifically exempted by rule of the board.

~~(6)~~(7) "Meat" means the edible flesh of livestock or poultry and includes livestock and poultry products. This term does not include cell-cultured edible products as defined in this section.

~~(7)~~(8) "Misbranded" means the term applied to meat:

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

(b) if it is offered for sale under the name of another food;

(c) if it is not derived from the edible flesh of livestock or poultry or livestock and poultry products;

~~(c)~~(d) if it is an imitation of a meat product, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter the name of the food being imitated;

~~(d)~~(e) if its container is so made, formed, or filled as to be misleading;

~~(e)~~(f) if it does not bear a label showing:

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

(ii) an accurate statement of the quantity of the product in terms of weight, measure, or numerical count. The board may adopt rules exempting small meat packages, meat not in containers, and other reasonable variations.

~~(f)~~(g) if any word, statement, or other information required by 81-9-216 through 81-9-220 and 81-9-226 through 81-9-236 to appear on the label is not prominently placed on the label, as compared with other words, statements, designs, or devices in the labeling, and is not stated in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

~~(g)~~(h) if it is represented as a food for which a definition and standard of identity or composition has been prescribed by the rules of the board, unless:

(i) it conforms to the definition and standard; and

(ii) its label bears the name of the food specified in the definition and standard and, if required by the rules, the common names of optional ingredients present in the food, other than spices, flavoring, and coloring;

~~(h)~~(i) if it is represented as a food for which a standard of fill of container has been prescribed by rules of the board and it falls below the standard of fill of container applicable to the food, unless its label bears, in the manner and form that the rules specify, a statement that it falls below the standard;

~~(i)~~(j) if it is not subject to the provisions of subsection ~~(7)(g)~~ (8)(h), unless its label bears:

(i) the common or usual name of the food, if any; and

(ii) in case it is fabricated from two or more ingredients, the common or usual name of each ingredient, except that spices, flavorings, and colorings may, when authorized by the board, be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of this subsection ~~(7)(i)(ii)~~ (8)(j)(ii) is impracticable or results in deception or unfair competition, exemptions must be established by rules promulgated by the board.

~~(j)~~(k) if it purports to be for special dietary uses, unless its label bears information concerning its vitamin, mineral, and other dietary properties as the board, after consultation with the U.S. secretary of agriculture, by rule prescribes as necessary in order to fully inform purchasers as to its value for those uses;

~~(k)~~(l) 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 ~~(7)(k)~~ (8)(l) is impracticable, exemptions must be established by rules promulgated by the board; or

~~(l)~~(m) 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.

~~(8)~~(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).

~~(9)~~(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.

~~(10)~~(11) "Pesticide chemical", "food additive", "color additive", and "raw agricultural commodity" have the same meanings as provided in 21 U.S.C. 321.

~~(11)~~(12) "Poultry" means any domesticated bird, whether alive or dead.

~~(12)~~(13) "Prepared" means slaughtered, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed."

- END -