A-Engrossed House Bill 2256

Ordered by the House March 2 Including House Amendments dated March 2

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of Governor Kate Brown for State Department of Agriculture)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

Makes dietary supplements, as defined, food for purposes of Oregon Food Law and laws regulating sanitation for food and food establishments.

1 A BILL FOR AN ACT

Relating to State Department of Agriculture regulation of dietary supplements; amending ORS 616.205, 616.695 and 632.705.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 616.205 is amended to read:

- 616.205. As used in ORS 616.205 to 616.385, unless the context clearly indicates a different meaning:
- (1) "Advertisement" includes all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of the food.
 - (2) "Color" includes black, white and intermediate grays.
- (3)(a) "Color additive" means a material that:
- (A) Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; or
- (B) When added or applied to a food or to the human body or any part thereof, is capable, alone or through reaction with other substance, of imparting color thereto.
- (b) "Color additive" does not include any material that has been exempted under the federal Act.
 - (c) Notwithstanding paragraph (a) of this subsection, "color additive" does not include any pesticide chemical, soil or plant nutrient, or other agricultural chemical 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 and thereby affecting its color, whether before or after harvest.
 - (4) "Consumer commodity" means any food as defined by ORS 616.205 to 616.215, 616.225 to 616.256, 616.286, 616.295, 616.310, 616.315, 616.325, 616.330, 616.341, 616.350 to 616.366, 616.790 and 616.992 or by the federal Act.
 - (5) "Contaminated with filth" means the condition of any food not securely protected from dust, dirt and, as far as may be necessary by all reasonable means, from all foreign or injurious sub-

NOTE: Matter in **boldfaced** type in an amended section is new; matter [italic and bracketed] is existing law to be omitted. New sections are in **boldfaced** type.

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- (6) "Dietary ingredient" means one or more of the following or a concentrate, constituent, extract or metabolite of one or more of the following:
- 4 (a) An amino acid;
- 5 (b) An herb or other botanical;
 - (c) A mineral;
 - (d) A dietary substance intended to supplement the human diet by increasing total dietary intake; or
 - (e) A vitamin.
 - (7) "Dietary supplement" means an article, not including any tobacco product, that:
 - (a) Is subject to dietary supplement labeling requirements under 21 C.F.R. 101.36;
 - (b) Is intended to supplement conventional food in the diet of humans and contains a dietary ingredient; and
- 14 (c)(A) Is intended for ingestion in tablet, capsule, powder, softgel, gelcap or liquid form; 15 or
 - (B) Is not represented to be a conventional food or to be for use as the sole item of a meal or diet.
 - [(6)] (8) "Director" means the Director of Agriculture.
- 19 [(7)] (9) "Federal Act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq., 20 52 Stat. 1040 et seq.
 - [(8)] (10) "Food" means:
- 22 (a) Articles used for food or drink, including ice, for human consumption or food for dogs and cats;
 - (b) Chewing gum; [and]
 - (c) Dietary supplements; and
 - [(c)] (d) Articles used for components of any such article.
 - [(9)] (11) "Food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, and including any source of radiation intended for any such use, if such 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 or experience based on common use in food to be safe under the conditions of its intended use. "Food additive" does not include:
 - (a) A pesticide chemical in or on a raw agricultural commodity;
 - (b) A pesticide chemical to the extent that it is intended for use, or is used in the production, storage or transportation of any raw agricultural commodity; or
 - (c) A color additive.
 - [(10)] (12) "Food establishment" means:
 - (a) Any room, building, structure or place, used or intended for use, or operated for storing, preparing, compounding, manufacturing, processing, freezing, packaging, distributing, handling or displaying food.
 - (b) The ground upon which such place or business is operated or used and so much ground adjacent thereto as is also used in carrying on the business of the establishment. The State Department of Agriculture may prescribe such additional area or places which, although they may not be

- 1 contiguous or adjacent to the above area or establishment, may be included therein.
 - (c) Vehicles, machinery, equipment, utensils, tools, fixtures, implements and all other articles or items, used in operating or carrying on the business of a food establishment.
 - [(11)] (13) "Immediate container" does not include package liners.
 - [(12)] (14) "Label" means a display of written, printed or graphic matter upon the immediate container of any article. A requirement made under authority of ORS 616.205 to 616.215, 616.225 to 616.256, 616.286, 616.295, 616.310, 616.315, 616.325, 616.330, 616.341, 616.350 to 616.366, 616.790 and 616.992 that any word, statement or other information appears on a label has not been obeyed unless such word, statement or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article or unless such word, statement or information is easily legible through the outside container or wrapper.
 - [(13)] (15) "Labeling" means all labels and other written, printed or graphic matters upon an article or any of its containers or wrappers, or accompanying such article.
 - [(14)] (16) "Package" means any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers, but does not include:
 - (a) Shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers or processors, or to wholesale or retail distributors thereof; or
 - (b) Shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity.
 - [(15)] (17) "Pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances is a "pesticide" as defined in ORS 634.006.
 - [(16)] (18) "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.
 - [(17)] (19) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.
 - **SECTION 2.** ORS 616.695 is amended to read:
 - 616.695. As used in ORS 616.695 to 616.755, unless the context requires otherwise:
 - (1) "Department" means the State Department of Agriculture.
 - (2) "Dietary ingredient" means one or more of the following or a concentrate, constituent, extract or metabolite of one or more of the following:
 - (a) An amino acid;
 - (b) An herb or other botanical;
 - (c) A mineral;

- (d) A dietary substance intended to supplement the human diet by increasing total dietary intake; or
 - (e) A vitamin.
- (3) "Dietary supplement" means an article, not including any tobacco product, that:
 - (a) Is subject to dietary supplement labeling requirements under 21 C.F.R. 101.36;
- 43 (b) Is intended to supplement conventional food in the diet of humans and contains a 44 dietary ingredient; and
 - (c)(A) Is intended for ingestion in tablet, capsule, powder, softgel, gelcap or liquid form;

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- (B) Is not represented to be a conventional food or to be for use as the sole item of a meal or diet.
 - [(2)] (4) "Food establishment" means:
- (a) Any room, building, structure or place, used or intended for use, or operated for storing, preparing, compounding, manufacturing, processing, freezing, packaging, distributing, handling, salvaging or displaying food.
- (b) The ground upon which such place or business is operated or used and so much ground adjacent thereto as is also used in carrying on the business of the establishment. The department may prescribe such additional area or places which, although they may not be contiguous or adjacent to the above area or establishment, may be included therein.
- (c) Vehicles, machinery, equipment, utensils, tools, fixtures, implements, and all other articles or items, used in operating or carrying on the business of a food establishment.
- [(3)] (5) "Food" means any article used, or intended to be used, for food, ice, drink, confection, [or] condiment or dietary supplement, whether simple or compound, or any part or ingredient thereof or in the preparation thereof, and for human consumption.
- [(4)] (6) "Salvaging" means the business of reconditioning, repacking, relabeling, cleaning or culling of foods that have been damaged or adulterated as a result of fire, storm, flood, water, smoke, chemicals or commercial transit accident.

SECTION 3. ORS 632.705 is amended to read:

- 632.705. As used in ORS 632.705 to 632.815:
- (1) "Adulterated" has the meaning given that term in ORS 616.235.
 - (2) "At retail" means a sale or transaction between a retailer and a consumer.
 - (3) "Bulk sale" means the sale of eggs in containers other than consumer containers.
 - (4) "Candling" means the examination of the interior of eggs by the use of transmitted light used in a partially dark room or place.
 - (5) "Consumer" means any person who purchases eggs at retail or any restaurant, hotel, boarding house, bakery, or institution or concern that purchases eggs for serving to guests or patrons thereof, or for its own use in cooking or baking.
 - (6) "Consumer container" means a container in which eggs are packed for sale to consumers.
 - (7) "Container" means any box, case, basket, carton, sack, bag or other receptacle.
 - (8) "Department" means the State Department of Agriculture.
- 33 (9) "Egg handler" means any person who contracts for or obtains possession or control of any 34 eggs for:
 - (a) Sale to another egg handler or a retailer; or
 - (b) Processing and sale to another egg handler, a retailer or a consumer.
 - (10) "Egg products" means the white, yolk, or any part of eggs, in liquid, frozen, dried, or any other form, used, intended or held for use, in the preparation of, or to be a part of or mixed with, food or food products, for human consumption, excepting products that contain eggs only in a relatively small proportion or historically have not been in the judgment of the department considered by consumers as products of the egg industry.
- 42 (11) "Eggs" or "shell eggs" means eggs in the shell from chickens, turkeys, ducks, geese or any 43 other species of fowl.
- 44 (12) "Federal Act" means the federal Egg Products Inspection Act, 21 U.S.C. 1031 et seq., 84 45 Stat. 1620 et seq.

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- 1 (13) "Labeling" has the meaning given that term in ORS 616.205 [(13)].
 - (14) "Lot" means an identifiable and certain quantity, group or shipment of one grade or size of eggs of a particular producer, egg handler or retailer. Such identification and certainty may be determined by the department by container labeling of codes, numbers or dates, or invoices containing such data.
 - (15) "Misbranded" has the meaning given that term in ORS 616.250.
 - (16) "Pasteurize" means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable microorganisms, by such processes as may be prescribed by the department.
- 10 (17) "Processing" means manufacturing egg products, including breaking eggs or filtering, mix-11 ing, blending, pasteurizing, stabilizing, cooling, freezing, drying or packaging egg products.
 - (18) "Retailer" means any person who sells eggs to a consumer.
- 13 (19) "Sell" or "sale" means to sell, offer for sale, expose for sale, or have in possession for sale.

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