

IC 16-42-2

Chapter 2. Uniform Food, Drug, and Cosmetic Act: Adulteration or Misbranding of Foods

IC 16-42-2-1

Conformity to federal standards and definitions; promotion of honesty and fair dealing; optional ingredients

Sec. 1. (a) Whenever any definitions or standard of identity, quality, or fill of container for any food or class of food are promulgated under authority of the Federal Act or the Federal Meat Inspection Act of 1907, as amended, the state department shall adopt definitions and standards for Indiana.

(b) Whenever, with regard to any other food or class of food, the state department finds that such action will promote honesty and fair dealing in the interest of consumers, the state department shall adopt rules establishing for any food or class of food:

- (1) a reasonable definition and standard of identity; and
- (2) a reasonable standard of quality and fill of container.

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

As added by P.L.2-1993, SEC.25.

IC 16-42-2-1.1

Duties of state veterinarian and state board of animal health

Sec. 1.1. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-17-5 or IC 15-18-1.

As added by P.L.137-1996, SEC.69. Amended by P.L.2-2008, SEC.42.

IC 16-42-2-2

Adulterated foods

Sec. 2. (a) A food is considered adulterated under any of the following conditions:

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

- (2) If:
- (A) the food bears or contains any added poison or added deleterious substance (other than a poison or a deleterious substance that is a pesticide chemical in or on a raw agricultural commodity, a food additive, or a color additive) that is unsafe within the meaning of section 5 of this chapter;
 - (B) the food is a raw agricultural commodity and the food bears or contains a pesticide chemical that is unsafe under section 5 of this chapter; or
 - (C) the food is or contains a food additive that is unsafe under section 5 of this chapter.

However, when a pesticide chemical is used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under section 5 of this chapter 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, notwithstanding section 5 of this chapter and clause (C) is not considered 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 residues in the processed food, when ready to eat, is not greater than the tolerance prescribed for the raw agricultural commodity.

- (3) If the food consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance or if the food is otherwise unfit for food.
- (4) If the food has been produced, transported, handled, prepared, packed, or held under unsanitary conditions or in unsanitary containers as the result of which the food may have become contaminated with filth or made diseased, unwholesome, or injurious to health.
- (5) If the food is, in whole or in part, the product of:
 - (A) a diseased animal;
 - (B) an animal that has died otherwise than by slaughter; or
 - (C) an animal that has been fed upon the uncooked offal from a slaughterhouse.
- (6) If the food's container is composed in whole or in part of any poisonous or deleterious substance that may make the contents injurious to health.
- (7) If the food has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a rule or an exemption in effect under section 5 of this chapter.
- (8) If any valuable constituent has been in whole or in part omitted or abstracted from the food.
- (9) If any substance has been substituted wholly or in part.
- (10) If damage or inferiority has been concealed in any manner.
- (11) If any substance has been added to the food or mixed or

packed with the food to:

- (A) increase the food's bulk or weight;
- (B) reduce the food's quality or strength;
- (C) make the food appear better or of greater value than the food is; or
- (D) create a deceptive appearance.

(12) If the food bears or contains a coal-tar color other than one from a batch that has been certified by the federal Food and Drug Administrator, as provided by regulations promulgated under authority of the Federal Act.

(13) If the food is a confectionery and has partially or completely imbedded in the food any nonnutritive object. However, this subdivision does not apply in the case of any nonnutritive object if, in the judgment of the state department as provided by rules, the nonnutritive object is of practical, functional value to the confectionery product and would not make the product injurious or hazardous to health.

(14) If the food is a confectionery and bears or contains any alcohol other than alcohol not in excess of one-half of one percent (0.5%) by volume derived solely from the use of flavoring extracts.

(15) If the food is a confectionery and bears or contains any nonnutritive substance. However, this subdivision does not apply to a safe, nonnutritive substance if:

(A) the nonnutritive substance is in or on a confectionery for a practical, functional purpose in the manufacture, packaging, or storing of the confectionery; and

(B) the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of IC 16-42-1 through IC 16-42-4. In addition, the state department may, for the purpose of avoiding or resolving uncertainty as to the application of this subdivision, adopt rules allowing or prohibiting the use of particular nonnutritive substances.

(16) If the food falls below the standard of purity, quality, or strength that the food purports or is represented to possess.

(17) If the food is or bears or contains any color additive that is unsafe under section 5 of this chapter.

(b) Subsection (a)(8) and (a)(9) do not prohibit:

- (1) the removal of butterfat from; or
- (2) the addition of skim milk to;

dairy products that comply with the definitions and standards for dairy products adopted by the state department.

As added by P.L.2-1993, SEC.25.

IC 16-42-2-3

Misbranded foods

Sec. 3. A food is considered to be misbranded under any of the

following conditions:

- (1) If the food's labeling is false or misleading in any way.
- (2) If the food's labeling or packaging fails to conform with the rules adopted under IC 16-42-1-2.
- (3) If the food is offered for sale under the name of another food.
- (4) If the food is an imitation of another food, unless the food's label bears, in type of uniform size and prominence, the word "imitation" and, immediately following that term, the name of the food imitated.
- (5) If the food's container is so made, formed, or filled as to be misleading.
- (6) If the food is in package form, unless the food bears a label containing the following:
 - (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. However, reasonable variations shall be permitted under this clause and exemptions for small packages shall be established by rules adopted by the state department.
- (7) If any word, statement, or other information required under IC 16-42-1 through IC 16-42-4 to appear on the label or labeling is not prominently placed on the food with the conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms that make the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (8) If the food purports to be or is represented as a food for which a definition and standard of identity has been prescribed by rules under section 1 of this chapter, unless:
 - (A) the food conforms to that definition and standard; and
 - (B) the food's label bears the name of the food specified in the definition and standard, and, insofar as may be required by those rules, the common names of optional ingredients (other than spices, flavoring, and coloring) present in the food.

This subdivision with respect to artificial coloring does not apply to butter, cheese, or ice cream.

- (9) If the food purports to be or is represented as:
 - (A) a food for which a standard of quality has been prescribed by rules as provided by section 1 of this chapter and the food's quality falls below that standard, unless the label bears, in the manner and form as the rules specify, a statement that the food falls below that standard; or
 - (B) a food for which a standard or standards of fill of container have been prescribed by rule under section 1 of this chapter and the food falls below the applicable standard

of fill of container unless the food's label bears, in such manner and form as the rules specify, a statement that the food falls below that standard.

(10) If the food is not subject to subdivision (8), unless the food's label bears:

- (A) the common or usual name of the food, if any; and
- (B) if the food is fabricated from at least two (2) ingredients, the common or usual name of each ingredient. However, spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each. In addition, to the extent that compliance with this clause is impracticable or results in deception or unfair competition, the state department shall establish exemptions by rule.

This subdivision with respect to artificial coloring does not apply to butter, cheese, or ice cream.

(11) If the food purports to be or is represented to be for special dietary uses, unless the food's label bears information concerning the food's vitamin, mineral, and other dietary properties that the state department determines to be, and by rules prescribes as necessary to fully inform purchasers as to the food's value for such uses.

(12) If the food bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless the food bears labeling stating that fact. However, to the extent that compliance with the requirements of this subdivision is impracticable, the state department shall establish exemptions by rule. This subdivision:

- (A) with respect to artificial coloring, does not apply to butter, cheese, or ice cream; and
- (B) with respect to chemical preservatives, does not apply to a pesticide chemical when used in or on a raw agricultural commodity that is the product of the soil.

As added by P.L.2-1993, SEC.25.

IC 16-42-2-4

Food in transit for repackaging or relabeling

Sec. 4. Food that, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where the food was originally processed or packed, is exempt from the affirmative labeling requirements of IC 16-42-1 through IC 16-42-4 while the food is in transit in intrastate commerce from one (1) establishment to the other, if such transit is made in good faith for completion purposes only. However, the food is otherwise subject to all the applicable provisions of IC 16-42-1 through IC 16-42-4.

As added by P.L.2-1993, SEC.25.

IC 16-42-2-5

Poisonous or deleterious substances; regulations

Sec. 5. (a) Any added poisonous or deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity or any color additive, with respect to any particular use or intended use, are considered unsafe for the purpose of application of:

- (1) section 2(a)(2) of this chapter with respect to any food;
- (2) IC 16-42-3-3(1) through IC 16-42-3-3(5) with respect to any drug or device; or
- (3) IC 16-42-4-2(1) with respect to any cosmetic;

unless there is in effect a rule under IC 16-42-1-2 or this section limiting the quantity of the substance and unless the use or intended use of the substance conforms to the terms prescribed by rule. While the rules regarding the substance are in effect, a food, drug, or cosmetic is not, by reason of bearing or containing the substance in accordance with the rules, to be considered adulterated within the meaning of section 2(a)(1) of this chapter, IC 16-42-3-3(1) through IC 16-42-3-3(5), or IC 16-42-4-2(1).

(b) The state department may, whenever public health or other considerations in Indiana require and upon the state department's own motion or upon the petition of an interested party, adopt, amend, or repeal rules (whether or not in accordance with regulations promulgated under the Federal Act) that do the following:

- (1) Prescribe tolerances for any of the following:
 - (A) Any added, poisonous, or deleterious substances.
 - (B) Food additives.
 - (C) Pesticide chemicals in or on raw agricultural commodities.
 - (D) Color additives.

This includes zero tolerances and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities.

- (2) Prescribe the conditions under which a food additive or a color additive may be safely used and exemptions where the food additive or color additive is to be used solely for investigational or experimental purposes.

(c) It is incumbent upon an interested party who petitions that a rule be adopted under subsection (b) to establish, by data submitted to the state health commissioner or the commissioner's legally authorized agent, that:

- (1) a necessity exists for the rule; and
- (2) the rule's effect will not be detrimental to the public health.

(d) If the data furnished by an interested party who petitions that a rule be adopted under subsection (b) is not sufficient to allow the state department to determine whether the rule should be adopted, the state department may require additional data to be submitted. Failure to comply with such a request is sufficient grounds to deny

the request.

(e) In adopting, amending, or repealing rules regarding such substances, the state department shall consider, among other relevant factors, the following items that are required to be furnished by the interested party who petitions for the adoption of a rule, if any:

(1) The name and all pertinent information concerning the substance, including if available the following:

(A) The chemical identity and composition of the substance.

(B) A statement of the conditions of the proposed use, including directions, recommendations, and suggestions, and specimens of proposed labeling.

(C) All relevant data bearing on the physical or other technical effect and the quantity required to produce that effect.

(2) The probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of that substance.

(3) The probable consumption of the substance in the diet of man and animals, taking into account any chemically or pharmacologically related substance in the diet.

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

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

(A) The substance in or on an article.

(B) Any substance formed in or on such article because of the use of that substance.

(C) The pure substance and all intermediates and impurities.

(6) Facts supporting a contention that the proposed use of the substance will serve a useful purpose.

As added by P.L.2-1993, SEC.25.

IC 16-42-2-6

Unfit perishable articles; condemnation or destruction

Sec. 6. (a) Any dairy product, meat, meat product, seafood, poultry, confectionery, bakery product, vegetable, fruit, or other perishable article:

(1) that is unsound;

(2) that contains any filthy, decomposed, or putrid substance; or

(3) that may be poisonous or deleterious to health or otherwise unsafe;

constitutes a nuisance.

(b) Whenever the state health commissioner or the commissioner's authorized agent finds:

(1) in any room, building, vehicle of transportation, or other structure; or

(2) on any premises;

perishable food or a food product which constitutes a nuisance under this section, the state health commissioner or the commissioner's authorized agent shall condemn or destroy the food or food product or in any other manner make the food or food product unsaleable as human food.

As added by P.L.2-1993, SEC.25.

IC 16-42-2-7

PCB contaminated livestock and poultry; indemnification

Sec. 7. (a) The state department shall indemnify livestock and poultry producers who, as a result of the direction of a state agency, are required after January 1, 1976, to remove livestock, livestock products, poultry, or poultry products of the producers from commercial markets because of contamination by polychlorinated biphenyls (PCB's).

(b) Indemnity may not be paid for any contamination that is the result of an intentional act of the livestock or poultry producer or that results from the continuous use of a known contaminated feed or water supply.

(c) Indemnity compensation shall be paid for losses incurred in the preceding calendar year and may not exceed eighty percent (80%) of the average commercial market value of the livestock, livestock product, poultry, or poultry product, less any indemnity received from another state or federal agency, for the period the producer is unable to sell the products. However, the aggregate indemnity compensation paid may not exceed the appropriation for any fiscal year.

(d) For purposes of this section, the commercial market value of livestock subject to indemnity compensation shall be determined as of the time of condemnation.

(e) The state department may adopt rules under IC 4-22-2 for the administration of this section.

(f) The state has the power of subrogation against any third party for indemnity amounts paid.

As added by P.L.2-1993, SEC.25.

IC 16-42-2-8

Recipe or teaching adulteration or imitation of foods; offense

Sec. 8. A person who:

(1) knowingly sells, offers for sale, trades, or gives away a recipe or formula for the adulteration or imitation of food; or

(2) knowingly teaches or offers to teach any method or means of adulterating any article of food or means of producing or manufacturing any imitation of any article of food;

commits a Class B misdemeanor.

As added by P.L.2-1993, SEC.25.

IC 16-42-2-9

Chapter violations; offenses

Sec. 9. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

As added by P.L.2-1993, SEC.25.