

the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) — percent (or %) —," or "— percent (or %) —" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "— percent (or %) —" shall appear following or directly below the word "containing" (or "contains"), or directly below the part of the common or usual name of the food required by paragraph (a) of this section when the word "containing" (or "contains") is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(c) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in this part.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) —" or "containing (or contains) no —" or "no —" or "does not contain —," with the blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (c) (1) and/or (2) of this section shall appear following or directly below the part of the common or usual name of the food required by paragraphs (a) and (b) of this section, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraph (b)(2) (i) and (ii) of this section.

(d) A common or usual name of a food may be established by common usage or by establishment of a regulation in this part, in a standard of identity, or in other regulations in this chapter.

[41 FR 38627, Sept. 10, 1976. Redesignated at 42 FR 14091, Mar. 15, 1977]

§ 502.19 Petitions.

(a) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who

has submitted a petition, may publish a proposal to issue, amend, or revoke, under this part, a regulation prescribing a common or usual name for a food, pursuant to part 10 of this chapter.

(b) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative, e.g., a smaller type size. A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted pursuant to part 10 of this chapter.

[42 FR 4716, Jan. 25, 1977; 42 FR 10980, Feb. 25, 1977. Redesignated at 42 FR 14091, Mar. 15, 1977, and amended at 42 FR 15675, Mar. 22, 1977; 42 FR 24254, May 13, 1977]

PART 509—UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL

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AUTHORITY: 21 U.S.C. 336, 342, 346, 346a, 348, 371.

SOURCE: 42 FR 52821, Sept. 30, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 509.3 Definitions and interpretations.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A *naturally occurring poisonous or deleterious substance* is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An *added poisonous or deleterious substance* is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) *Food* includes pet food, animal feed, and substances migrating to food from food-contact articles.

§ 509.4 Establishment of tolerances, regulatory limits, and action levels.

(a) When appropriate under the criteria of § 509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b) When appropriate under the criteria of § 509.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c)(1) When appropriate under the criteria of § 509.6, an action level for an