

**§ 502.19**

(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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**Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]**

**Subpart D—Naturally Occurring Poisonous or Deleterious Substances [Reserved]**

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 added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Division of Dockets Management before the notice is published. The notice shall invite public comment on the action level.

(d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

[42 FR 52821, Sept. 30, 1977, as amended at 55 FR 20786, May 21, 1990]

#### § 509.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 10.30 of this

chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

[42 FR 52821, Sept. 30, 1977, as amended at 54 FR 18280, Apr. 28, 1989]

#### § 509.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under sections 406, 408, or 409 of the act by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (d) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent of which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of