usage or by establishment of a regulation in this part, in a standard of identity, or in other regulations in this chapter.


§ 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.


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

Subpart A—General Provisions

Sec.
509.3 Definitions and interpretations.
509.4 Establishment of tolerances, regulatory limits, and action levels.
509.5 Petitions.
509.6 Added poisonous or deleterious substances.
509.7 Unavoidability.
509.15 Use of polychlorinated biphenyls (PCB’s) in establishments manufacturing food-packaging materials.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

509.30 Temporary tolerances for polychlorinated biphenyls (PCB’s).

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances

[Reserved]
Food and Drug Administration, HHS

§ 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 changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) A regulatory limit for an added poisonous or deleterious substance in any food may be established when each of the following criteria is met:

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

(2) The substance is not currently used in any food and cannot be avoided by good manufacturing practice.

(3) The substance is not a pesticide chemical and is not present in food at levels that are not expected to have adverse effects on human health.

(4) The use of the substance is not expected to cause significant adverse effects on human health or the environment.

(5) The use of the substance is not expected to cause significant economic injury to plants or animals.

§ 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.


§ 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.

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(4) The use of the substance is not expected to cause significant adverse effects on human health or the environment.

(5) The use of the substance is not expected to cause significant economic injury to plants or animals.

(6) The use of the substance is not expected to cause significant environmental impacts.

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