

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

PART 170—FOOD ADDITIVES

Subpart A—General Provisions

Sec.

- 170.3 Definitions.
- 170.6 Opinion letters on food additive status.
- 170.10 Food additives in standardized foods.
- 170.15 Adoption of regulation on initiative of Commissioner.
- 170.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.
- 170.18 Tolerances for related food additives.
- 170.19 Pesticide chemicals in processed foods.

Subpart B—Food Additive Safety

- 170.20 General principles for evaluating the safety of food additives.
- 170.22 Safety factors to be considered.
- 170.30 Eligibility for classification as generally recognized as safe (GRAS).
- 170.35 Affirmation of generally recognized as safe (GRAS) status.
- 170.38 Determination of food additive status.
- 170.39 Threshold of regulation for substances used in food-contact articles.

Subpart C—Specific Administrative Rulings and Decisions

- 170.45 Fluorine-containing compounds.
- 170.50 Glycine (aminoacetic acid) in food for human consumption.
- 170.60 Nitrites and/or nitrates in curing pre-mixes.

AUTHORITY: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

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Subpart A—General Provisions

§ 170.3 Definitions.

For the purposes of this subchapter, the following definitions apply:

- (a) *Secretary* means the Secretary of Health and Human Services.
- (b) *Department* means the Department of Health and Human Services.
- (c) *Commissioner* means the Commissioner of Food and Drugs.
- (d) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936, 52

Stat. 1040 *et seq.*, as amended (21 U.S.C. 301-392).

(e)(1) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. "Affecting the characteristics of food" does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(2) *Uses of food additives not requiring a listing regulation.* Substances used in food-contact articles (e.g., food-packaging and food-processing equipment) that migrate, or may be expected to migrate, into food at such negligible levels that they have been exempted from regulation as food additives under § 170.39.

(f) *Common use in food* means a substantial history of consumption of a substance for food use by a significant number of consumers.

(g) The word *substance* in the definition of the term "food additive" includes a food or food component consisting of one or more ingredients.

(h) *Scientific procedures* include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of