

§ 177.3

40 CFR Ch. I (7-1-04 Edition)

within the meaning of FFDCA section 409 unless a food additive regulation permitted that residue in or on the processed food.

§ 177.3 Definitions.

For the purposes of this part:

Administrator means the Administrator of the Agency, or an officer or employee of the Agency to whom the Administrator has delegated the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301-392.

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136-136y.

Food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of or otherwise affecting the characteristics of any food (including any such substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food), except that such term does not include:

(1) A pesticide chemical in or on a raw agricultural commodity.

(2) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity.

(3) A color additive.

(4) Any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to the FFDCA, the Poultry Products Inspection Act, or the Federal Meat Inspection Act.

(5) A new animal drug.

(6) A substance that is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

Food additive regulation means a regulation issued pursuant to FFDCA section 409 that states the conditions under which a food additive may be safely used. A food additive regulation under this part ordinarily establishes a tolerance for pesticide residues in or on a particular processed food or a group of such foods. It may also specify:

(1) The particular food or classes of food in or on which a food additive may be used.

(2) The maximum quantity of the food additive which may be used in or on such food.

(3) The manner in which the food additive may be added to or used in or on such food.

(4) Directions or other labeling or packaging requirements for the food additive.

Pesticide chemical means any substance which alone, or in chemical combination with or in formulation with one or more other substances, is a "pesticide" within the meaning of FIFRA and which is used in the production, storage, or transportation of any raw agricultural commodity or processed food. The term includes any substance that is an active ingredient, intentionally-added inert ingredient, or impurity of such a "pesticide."

Pesticide residue means a residue of a pesticide chemical or of any metabolite or degradation product of a pesticide chemical.

Tolerance means:

(1) The amount of a pesticide residue that legally may be present in or on a raw agricultural commodity under the terms of a tolerance under FFDCA section 408 or a processed food under the terms of a food additive regulation under FFDCA section 409. Tolerances are usually expressed in terms of parts of the pesticide residue per million parts of the food (ppm), by weight.

(2) [Reserved]

Subparts B-D [Reserved]