Subchapter B—Food for Human Consumption

Part 170—Food Additives

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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.

(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(h) Scientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.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
§ 170.3 of the report of the National Academy of Sciences/National Research Council report, “A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe” (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

1. Baked goods and baking mixes, including all ready-to-eat and ready-to-bake products, flours, and mixes requiring preparation before serving.

2. Beverages, alcoholic, including malt beverages, wines, distilled liquors, and cocktail mix.

3. Beverages and beverage bases, nonalcoholic, including only special or spiced teas, soft drinks, coffee substitutes, and fruit and vegetable flavored gelatin drinks.

4. Breakfast cereals, including ready-to-eat and instant and regular hot cereals.

5. Cheeses, including curd and whey cheeses, cream, natural, grating, pressed, spread, dip, and miscellaneous cheeses.

6. Chewin gum, including all forms.

7. Coffee and tea, including regular, decaffeinated, and instant types.

8. Condiments and relishes, including plain seasoning sauces and spreads, olives, pickles, and relishes, but not spices or herbs.

9. Confections and frostings, including candy and flavored frostings, marshmallows, baking chocolate, and brown, lump, rock, maple, powdered, and raw sugars.

10. Dairy product analogs, including nondairy milk, frozen or liquid creamers, coffee whiteners, toppings, and other nondairy products.

11. Egg products, including liquid, frozen, or dried eggs, and egg dishes made therefrom, i.e., egg roll, egg foo young, egg salad, and frozen multicourse egg meals, but not fresh eggs.

12. Fats and oils, including margarine, dressings for salads, butter, salad oils, shortenings and cooking oils.

13. Fish products, including all prepared main dishes, salads, appetizers,
(14) Fresh eggs, including cooked eggs and egg dishes made only from fresh shell eggs.
(15) Fresh fish, including only fresh and frozen fish, shellfish, and other aquatic animals.
(16) Fresh fruits and fruit juices, including only raw fruits, citrus, melons, and berries, and home-prepared “ades” and punches made therefrom.
(17) Fresh meats, including only fresh or home-frozen beef or veal, pork, lamb or mutton and home-prepared fresh meat-containing dishes, salads, appetizers, or sandwich spreads made therefrom.
(18) Fresh poultry, including only fresh or home-frozen poultry and game birds and home-prepared fresh poultry-containing dishes, salads, appetizers, or sandwich spreads made therefrom.
(19) Fresh vegetables, tomatoes, and potatoes, including only fresh and home-prepared vegetables.
(20) Frozen dairy desserts and mixes, including ice cream, ice milks, sherbets, and other frozen dairy desserts and specialties.
(21) Fruit and water ices, including all frozen fruit and water ices.
(22) Gelatins, puddings, and fillings, including flavored gelatin desserts, puddings, custards, parfaits, pie fillings, and gelatin base salads.
(23) Grain products and pastas, including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables.
(24) Gravies and sauces, including all meat sauces and gravies, and tomato, milk, buttery, and specialty sauces.
(25) Hard candy and cough drops, including all hard type candies.
(26) Herbs, seeds, spices, seasonings, blends, extracts, and flavorings, including all natural and artificial spices, blends, and flavors.
(27) Jams and jellies, home-prepared, including only home-prepared jams, jellies, fruit butters, preserves, and sweet spreads.
(28) Jams and jellies, commercial, including only commercially processed jams, jellies, fruit butters, preserves, and sweet spreads.
(29) Meat products, including all meats and meat containing dishes, salads, appetizers, frozen multicourse meat meals, and sandwich ingredients prepared by commercial processing or using commercially processed meats with home preparation.
(30) Milk, whole and skim, including only whole, lowfat, and skim fluid milks.
(31) Milk products, including flavored milks and milk drinks, dry milks, toppings, snack dips, spreads, weight control milk beverages, and other milk origin products.
(32) Nuts and nut products, including whole or shelled tree nuts, peanuts, coconut, and nut and peanut spreads.
(33) Plant protein products, including the National Academy of Sciences/National Research Council “reconstituted vegetable protein” category, and meat, poultry, and fish substitutes, analogs, and extender products made from plant proteins.
(34) Poultry products, including all poultry and poultry-containing dishes, salads, appetizers, frozen multicourse poultry meals, and sandwich ingredients prepared by commercial processing or using commercially processed poultry with home preparation.
(35) Processed fruits and fruit juices, including all commercially processed fruits, citrus, berries, and mixtures; salads, juices and juice punches, concentrates, dilutions, “ades”, and drink substitutes made therefrom.
(36) Processed vegetables and vegetable juices, including all commercially processed vegetables, vegetable dishes, frozen multicourse vegetable meals, and vegetable juices and blends.
(37) Snack foods, including chips, pretzels, and other novelty snacks.
(38) Soft candy, including candy bars, chocolates, fudge, mints, and other chewy or nougat candies.
(39) Soups, home-prepared, including meat, fish, poultry, vegetable, and combination home-prepared soups.
(40) Soups and soup mixes, including commercially prepared meat, fish, poultry, vegetable, and combination soups and soup mixes.
(41) Sugar, white, granulated, including only white granulated sugar.
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(42) Sugar substitutes, including granulated, liquid, and tablet sugar substitutes.

(43) Sweet sauces, toppings, and syrups, including chocolate, berry, fruit, corn syrup, and maple sweet sauces and toppings.

The following terms describe the physical or technical functional effects for which direct human food ingredients may be added to foods. They are adopted from the National Academy of Sciences/National Research Council national survey of food industries, reported to the Food and Drug Administration under the contract title “A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe” (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408:

(1) “Anticaking agents and free-flow agents”: Substances added to finely powdered or crystalline food products to prevent caking, lumping, or agglomeration.

(2) “Antimicrobial agents”: Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under “preservatives.”

(3) “Antioxidants”: Substances used to preserve food by retarding deterioration, rancidity, or discoloration due to oxidation.

(4) “Colors and coloring adjuncts”: Substances used to impart, preserve, or enhance the color or shading of a food, including color stabilizers, color fixatives, color-retention agents, etc.

(5) “Curing and pickling agents”: Substances imparting a unique flavor and/or color to a food, usually producing an increase in shelf-life stability.

(6) “Dough strengtheners”: Substances used to modify starch and gluten, thereby producing a more stable dough, including the applicable effects listed by the National Academy of Sciences/National Research Council under “dough conditioner.”

(7) “Drying agents”: Substances with moisture-absorbing ability, used to maintain an environment of low moisture.

(8) “Emulsifiers and emulsifier salts”: Substances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.

(9) “Enzymes”: Enzymes used to improve food processing and the quality of the finished food.

(10) “Firming agents”: Substances added to precipitate residual pectin, thus strengthening the supporting tissue and preventing its collapse during processing.

(11) “Flavor enhancers”: Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.

(12) “Flavoring agents and adjuvants”: Substances added to impart or help impart a taste or aroma in food.

(13) “Flour treating agents”: Substances added to milled flour, at the mill, to improve its color and/or baking qualities, including bleaching and maturing agents.

(14) “Formulation aids”: Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.

(15) “Fumigants”: Volatile substances used for controlling insects or pests.

(16) “Humectants”: Hygroscopic substances incorporated in food to promote retention of moisture, including moisture-retention agents and anti-dusting agents.

(17) “Leavening agents”: Substances used to produce or stimulate production of carbon dioxide in baked goods to impart a light texture, including yeast, yeast foods, and calcium salts listed by the National Academy of Sciences/National Research Council under “dough conditioners.”

(18) “Lubricants and release agents”: Substances added to food contact surfaces to prevent ingredients and finished products from sticking to them.
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(19) “Non-nutritive sweeteners”: Substances having less than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

(20) “Nutrient supplements”: Substances which are necessary for the body’s nutritional and metabolic processes.

(21) “Nutritive sweeteners”: Substances having greater than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

(22) “Oxidizing and reducing agents”: Substances which chemically oxidize or reduce another food ingredient, thereby producing a more stable product, including the applicable effect listed by the National Academy of Sciences/National Research Council under “dough conditioners.”

(23) “pH control agents”: Substances added to change or maintain active acidity or basicity, including buffers, acids, alkalies, and neutralizing agents.

(24) “Processing aids”: Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, catalysts, flocculents, filter aids, and crystallization inhibitors, etc.

(25) “Propellants, aerating agents, and gases”: Gases used to supply force to expel a product or used to reduce the amount of oxygen in contact with the food in packaging.

(26) “Sequestrants”: Substances which combine with polyvalent metal ions to form a soluble metal complex, to improve the quality and stability of products.

(27) “Solvents and vehicles”: Substances used to extract or dissolve another substance.

(28) “Stabilizers and thickeners”: Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodifying agents, setting agents, jellying agents, and bulking agents, etc.

(29) “Surface-active agents”: Substances used to modify surface properties of liquid food components for a variety of effects, other than emulsifiers, but including solubilizing agents, dispersants, detergents, wetting agents, rehydration enhancers, whipping agents, foaming agents, and defoaming agents, etc.

(30) “Surface-finishing agents”: Substances used to increase palatability, preserve gloss, and inhibit discoloration of foods, including glazes, polishes, waxes, and protective coatings.

(31) “Synergists”: Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.

(32) “Texturizers”: Substances which affect the appearance or feel of the food.


§ 170.6 Opinion letters on food additive status.

(a) Over the years the Food and Drug Administration has given informal written opinions to inquiries as to the safety of articles intended for use as components of, or in contact with, food. Prior to the enactment of the Food Additives Amendment of 1958 (Pub. L. 85-929; Sept. 6, 1958), these opinions were given pursuant to section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, which reads in part: “A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health”.

(b) Since enactment of the Food Additives Amendment, the Food and Drug Administration has advised such inquirers that an article:

(1) Is a food additive within the meaning of section 201(s) of the act; or
(2) Is generally recognized as safe (GRAS); or
(3) Has prior sanction or approval under that amendment; or
(4) Is not a food additive under the conditions of intended use.

(c) In the interest of the public health, such articles which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1), or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food...
§ 170.10 Food additives in standardized foods.

(a) The inclusion of food ingredients in parts 170 through 189 of this chapter does not imply that these ingredients may be used in standardized foods unless they are recognized as optional ingredients in applicable food standards. Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the Act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in this part shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the Act requires that the Secretary publish notice of a petition for the establishment of a food-additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food-additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food-additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this part.

(c) A regulation will not be issued allowing the use of a food additive in a food for which a definition and standard of identity is established, unless its issuance is in conformity with section 401 of the Act or with the terms of a temporary permit issued under § 130.17 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the food additive regulation will be conditioned on such compliance and will expire with the expiration of the temporary permit.

§ 170.15 Adoption of regulation on initiative of Commissioner.

(a) The Commissioner upon his own initiative may propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. Notice of such proposal shall be published in the Federal Register and shall state the reasons for the proposal.

(b) Action upon a proposal made by the Commissioner shall proceed as provided in part 10 of this chapter.
§ 170.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

A food additive or food containing a food additive intended for investigational use by qualified experts shall be exempt from the requirements of section 409 of the Act under the following conditions:

(a) If intended for investigational use in vitro or in laboratory research animals, it bears a label which states prominently, in addition to the other information required by the act, the warning:

Caution. Contains a new food additive for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(b) If intended for use in animals other than laboratory research animals and if the edible products of the animals are to be marketed as food, permission for the marketing of the edible products as food has been requested by the sponsor, and authorization has been granted by the Food and Drug Administration in accordance with § 511.1 of this chapter or by the Department of Agriculture in accordance with 9 CFR 309.17, and it bears a label which states prominently, in addition to the other information required by the Act, the warning:

Caution. Contains a new food additive for use only in investigational animals. Not for use in humans.

(c) If intended for nonclinical laboratory studies in food-producing animals, the study is conducted in compliance with the regulations set forth in part 58 of this chapter.


§ 170.19 Pesticide chemicals in processed foods.

When pesticide chemical residues occur in processed foods due to the use of raw agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted or a tolerance prescribed under section 408 of the Act, the processed food will not be regarded as adulterated so long as good manufacturing practice has been followed in removing having additive toxic effects and will be considered as related food additives. (b) Tolerances established for such related food additives may limit the amount of a common component that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present or may limit the total amount of related food additives that may be present.

(c) Where food additives from two or more chemicals in the same class are present in or on a food, the tolerance for the total of such additives shall be the same as that for the additive having the lowest numerical tolerance in this class, unless there are available methods that permit quantitative determination of the amount of each food additive present or unless it is shown that a higher tolerance is reasonably required for the combined additives to accomplish the physical or technical effect for which such combined additives are intended and that the higher tolerance will be safe.

(d) Where residues from two or more additives in the same class are present in or on a food and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

(1) Determine the quantity of each residue present.
(2) Divide the quantity of each residue by the tolerance that would apply if it occurred alone, and multiply by 100 to determine the percentage of the permitted amount of residue present.
(3) Add the percentages so obtained for all residues present.
(4) The sum of the percentage shall not exceed 100 percent.

§ 170.18 Tolerances for related food additives.

(a) Food additives that cause similar or related pharmacological effects will be regarded as a class, and in the absence of evidence to the contrary, as
any residue from the raw agricultural commodity in the processing (such as by peeling or washing) and so long as the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. But when the concentration of residue in the processed food when ready to eat is higher than the tolerance prescribed for the raw agricultural commodity, the processed food is adulterated unless the higher concentration is permitted by a tolerance obtained under section 409 of the Act. For example, if fruit bearing a residue of 7 parts per million of DDT permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated unless the higher tolerance for DDT is authorized by the regulations in this part. Food that is itself ready to eat, and which contains a higher residue than allowed for the raw agricultural commodity, may not be legalized by blending or mixing with other foods to reduce the residue in the mixed food below the tolerance prescribed for the raw agricultural commodity.

Subpart B—Food Additive Safety

§ 170.20 General principles for evaluating the safety of food additives.

(a) In reaching a decision on any petition filed under section 409 of the Act, the Commissioner will give full consideration to the specific biological properties of the compound and the adequacy of the methods employed to demonstrate safety for the proposed use, and the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council. A petition will not be denied, however, by reason of the petitioner’s having followed procedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures. In reaching a decision, the Commissioner will give due weight to the anticipated levels and patterns of consumption of the additive specified or reasonably inferable. For the purposes of this section, the principles for evaluating safety of additives set forth in the abovementioned publications will apply to any substance that may properly be classified as a food additive as defined in section 201(s) of the Act.

(b) Upon written request describing the proposed use of an additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a food additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 170.22 Safety factors to be considered.

In accordance with section 409(c)(5)(C) of the Act, the following safety factors will be applied in determining whether the proposed use of a food additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed \( \frac{1}{100} \) of the maximum amount demonstrated to be without harm to experimental animals.

§ 170.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.
(b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(c)(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

(2) A substance used in food prior to January 1, 1958, may be generally recognized as safe through experience based on its common use in food when that use occurred exclusively or primarily outside of the United States if the information about the experience establishes that the use of the substance is safe within the meaning of the act (see §170.3(i)). Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available in the country in which the history of use has occurred and readily available to interested qualified experts in that country. Persons claiming GRAS status for a substance based on its common use in food outside of the United States should obtain FDA concurrence that the use of the substance is GRAS.

(d) The food ingredients listed as GRAS in part 182 of this chapter or affirmed as GRAS in part 184 or §186.1 of this chapter do not include all substances that are generally recognized as safe for their intended use in food. Because of the large number of substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of food, it is impracticable to list all such substances that are GRAS. A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific inclusion in part 182, part 184 or §186.1 of this chapter.

(e) Food ingredients were listed as GRAS in part 182 of this chapter during 1958–1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to a prior sanction. All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in part 184 or §186.1 of this chapter.

(f) The status of the following food ingredients will be reviewed and affirmed as GRAS or determined to be a food additive or subject to a prior sanction pursuant to §170.35, §170.38, or §180.1 of this chapter:

(1) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, and which has been modified by processes first introduced into commercial use
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after January 1, 1958, which may reasonably be expected significantly to alter the composition of the substance.

(2) Any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effect, for which no health hazard is known, that has had significant alteration of composition by breeding or selection after January 1, 1958, where the change may be reasonably expected to alter the nutritive value or the concentration of toxic constituents.

(3) Distillates, isolates, extracts, and concentration of extracts of GRAS substances.

(4) Reaction products of GRAS substances.

(5) Substances not of a natural biological origin, including those for which evidence is offered that they are identical to a GRAS counterpart of natural biological origin.

(g) A food ingredient that is not GRAS or subject to a prior sanction requires a food additive regulation promulgated under section 409 of the act before it may be directly or indirectly added to food.

(h) A food ingredient that is listed as GRAS in part 182 of this chapter or affirmed as GRAS in part 184 or § 186.1 of this chapter shall be regarded as GRAS only if, in addition to all the requirements in the applicable regulation, it also meets all of the following requirements:

(1) It complies with any applicable food grade specifications of the Food Chemicals Codex, 2d Ed. (1972), or, if specifically indicated in the GRAS affirmation regulation, the Food Chemicals Codex, 3d Ed. (1981), which are incorporated by reference, except that any substance used as a component of articles that contact food and affirmed as GRAS in § 186.1 of this chapter shall comply with the specifications therein, or in the absence of such specifications, shall be of a purity suitable for its intended use. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(2) It performs an appropriate function in the food or food-contact article in which it is used.

(3) It is used at a level no higher than necessary to achieve its intended purpose in that food or, if used as a component of a food-contact article, at a level no higher than necessary to achieve its intended purpose in that article.

(i) If a substance is affirmed as GRAS in part 184 or § 186.1 of this chapter with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS. In such a case a manufacturer may not rely on the regulation as authorizing the use but must independently establish that the use is GRAS or must use the substance in accordance with a food additive regulation.

(j) If an ingredient is affirmed as GRAS in part 184 or § 186.1 of this chapter with specific limitation(s), it may be used in food only within such limitation(s) (including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use). Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(k) Pursuant to § 170.35, a food ingredient may be affirmed as GRAS in part 184 or § 186.1 of this chapter for a specific use(s) without a general evaluation of use of the ingredient. In addition to the use(s) specified in the regulation, other uses of such an ingredient may also be GRAS. Any affirmation of GRAS status for a specific use(s), without a general evaluation of use of the ingredient, is subject to reconsideration upon such evaluation.

(l) New information may at any time require reconsideration of the GRAS status of a food ingredient. Any change in part 182, part 184, or § 186.1 of this
§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

(a) The Commissioner, either on his initiative or on the petition of an interested person, may affirm the GRAS status of substances that directly or indirectly become components of food.

(b)(1) If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS, he will place all of the data and information on which he relies on public file in the office of the Dockets Management Branch and will publish in the Federal Register a notice giving the name of the substance, its proposed uses, and any limitations proposed for purposes other than safety.

(2) The Federal Register notice will allow a period of 60 days during which any interested person may review the data and information and/or file comments with the Dockets Management Branch. Copies of all comments received shall be made available for examination in the Dockets Management Branch’s office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS as described in §170.30, he will publish a notice in the Federal Register listing the substance as GRAS in part 182, part 184, or part 186 of this chapter, as appropriate.

(4) If, after evaluation of the comments, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS and that it should be considered a food additive subject to section 409 of the Act, he shall publish a notice thereof in the Federal Register in accordance with §170.38.

(c)(1) Persons seeking the affirmation of GRAS status of substances as provided in §170.30(e), except those subject to the NAS/NRC GRAS list survey (36 FR 20546; October 23, 1971), shall submit a petition for GRAS affirmation pursuant to part 10 of this chapter. Such petition shall contain information to establish that the GRAS criteria as set forth in §170.30 (b) or (c) have been met, in the following form:

(i) Description of the substance, including:

(a) Common or usual name.

(b) Chemical name.

(c) Chemical Abstract Service (CAS) registry number.

(d) Empirical formula.

(e) Structural formula.

(f) Specifications for food grade material, including arsenic and heavy metals. (Recommendation for any change in the Food Chemicals Codex monograph should be included where applicable.)

(g) Quantitative compositions.

(h) Manufacturing process (excluding any trade secrets).

(iii) Use of the substance, including:

(a) Date when use began.

(b) Information and reports or other data on past uses in food.

(c) Foods in which used, and levels of use in such foods, and for what purposes.

(d) Sensitivity and reproducibility of such method(s).

(iv) Information to establish the safety and functionality of the substance in food. Published scientific literature, evidence that the substance is identical to a GRAS counterpart of natural biological origin, and other data may be submitted to support safety. Any adverse information or consumer complaints shall be included. Complete bibliographic references shall be provided where a copy of the article is not provided.

(v) A statement signed by the person responsible for the petition that to the best of his knowledge it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the safety and functionality of the substance.

(vi) If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to
each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(vii) [Reserved]

(viii) A claim for categorical exclusion under §25.30 or §25.32 of this chapter or an environmental assessment under §25.40 of this chapter.

(2) Within 30 days after the date of filing the petition, the Commissioner will place the petition on public file in the office of the Dockets Management Branch and will publish a notice of filing in the FEDERAL REGISTER giving the name of the petitioner and a brief description of the petition including the name of the substance, its proposed use, and any limitations proposed for reasons other than safety. A copy of the notice will be mailed to the petitioner at the time the original is sent to the FEDERAL REGISTER.

(3) The notice of filing in the FEDERAL REGISTER will allow a period of 60 days during which any interested person may review the petition and/or file comments with the Dockets Management Branch. Copies of all comments received shall be made available for examination in the Dockets Management Branch's office.

(4) The Commissioner will evaluate the petition and all available information including all comments received. If the petition and such information provide convincing evidence that the substance is NOT GRAS as described in §170.30 he will publish an order in the FEDERAL REGISTER listing the substance as GRAS in part 182, part 184, or part 186 of this chapter, as appropriate.

(5) If, after evaluation of the petition and all available information, the Commissioner concludes that there is a lack of convincing evidence that the substance is NOT GRAS and is a food additive subject to section 409 of the Act, he shall publish a notice thereof in the FEDERAL REGISTER in accordance with §170.38.

(6) The notice of filing in the FEDERAL REGISTER will request submission of proof of any applicable prior sanction for use of the ingredient under conditions different from those proposed to be determined to be GRAS. The failure of any person to come forward with proof of such an applicable prior sanction in response to the notice of filing will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice of filing will also constitute a proposal to establish a regulation under part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the notice of filing.

(Information collection requirements were approved by the Office of Management and Budget under control number 0910-0132)

(3) The Commissioner will evaluate all comments received. If he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the Act, he will publish a notice thereof in the Federal Register. If he concludes that there is convincing evidence that the substance is GRAS, he will publish an order in the Federal Register listing the substance as GRAS in part 182, part 184, or part 186 of this chapter, as appropriate.

(c) A Federal Register notice determining that a substance is a food additive shall provide for the use of the additive in food or food contact surfaces as follows:

(1) It may promulgate a food additive regulation governing use of the additive.

(2) It may promulgate an interim food additive regulation governing use of the additive.

(3) It may require discontinuation of the use of the additive.

(4) It may adopt any combination of the above three approaches for different uses or levels of use of the additive.

(d) If the Commissioner of Food and Drugs is aware of any prior sanction for use of the substance, he will concurrently propose a separate regulation covering such use of the ingredient under part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal.

§170.39 Threshold of regulation for substances used in food-contact articles.

(a) A substance used in a food-contact article (e.g., food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if:

(1) The substance has not been shown to be a carcinogen in humans or animals, and there is no reason, based on the chemical structure of the substance, to suspect that the substance is a carcinogen. The substance must also not contain a carcinogenic impurity or, if it does, must not contain a carcinogenic impurity with a TD₅₀ value based on chronic feeding studies reported in the scientific literature or otherwise available to the Food and Drug Administration of less than 6.25 milligrams per kilogram bodyweight per day (The TD₅₀, for the purposes of this section, is the feeding dose that causes cancer in 50 percent of the test animals when corrected for tumors found in control animals. If more than one TD₅₀ value has been reported in the scientific literature for a substance, the Food and Drug Administration will use the lowest appropriate TD₅₀ value in its review);

(2) The substance presents no other health or safety concerns because:

(i) The use in question has been shown to result in or may be expected to result in dietary concentrations at or below 0.5 parts per billion, corresponding to dietary exposure levels at or below 1.5 micrograms/person/day (based on a diet of 1,500 grams of solid food and 1,500 grams of liquid food per person per day); or

(ii) The substance is currently regulated for direct addition into food, and the dietary exposure to the substance resulting from the proposed use is at or below 1 percent of the acceptable daily intake as determined by safety data in...
§ 170.39

the Food and Drug Administration's files or from other appropriate sources;

(3) The substance has no technical effect in or on the food to which it migrates; and

(4) The substance use has no significant adverse impact on the environment.

(b) Notwithstanding paragraph (a) of this section, the Food and Drug Administration reserves the right to decline to grant an exemption in those cases in which available information establishes that the proposed use may pose a public health risk. The reasons for the agency's decision to decline to grant an exemption will be explained in the Food and Drug Administration's response to the requestor.

(c) A request for the Food and Drug Administration to exempt a use of a substance from regulation as a food additive shall include three copies of the following information (if part of the submitted material is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate in accordance with §10.20(c)(2) of this chapter):

(1) The chemical composition of the substance for which the request is made, including, whenever possible, the name of the chemical in accordance with current Chemical Abstract Service (CAS) nomenclature guidelines and a CAS registry number, if available;

(2) Detailed information on the conditions of use of the substance (e.g., temperature, type of food with which the substance will come into contact, the duration of the contact, and whether the food-contact article will be for repeated or single use applications);

(3) A clear statement as to whether the request for exemption from regulation as a food additive is based on the fact that the use of the substance in the food-contact article results in a dietary concentration at or below 0.5 parts per billion, or on the fact that it involves the use of a regulated direct food additive for which the dietary exposure is at or below 1 percent of the acceptable dietary intake (ADI);

(4) Data that will enable the Food and Drug Administration to estimate the daily dietary concentration resulting from the proposed use of the substance. These data should be in the form of:

(i) Validated migration data obtained under worst-case (temperature) intended use conditions utilizing appropriate food simulating solvents;

(ii) Information on the amount of the substance used in the manufacture of the food-contact article; or

(iii) Information on the residual level of the substance in the food-contact article. For repeat-use articles, an estimate of the amount of food that contacts a specific unit of surface area over the lifetime of the article should also be provided. (In cases where data are provided only in the form of manufacturing use levels or residual levels of the substance present in the food-contact article, the Food and Drug Administration will calculate a worst-case dietary concentration level assuming 100 percent migration.) A detailed description of the analytical method used to quantify the substance should also be submitted along with data used to validate the detection limit.

(5) The results of an analysis of existing toxicological information on the substance and its impurities. This information on the substance is needed to show whether an animal carcinogen bioassay has been carried out, or whether there is some other basis for suspecting that the substance is a carcinogen or potent toxin. This type of information on the impurities is needed to show whether any of them are carcinogenic, and, if carcinogenic, whether their TD50 values are greater than 6.25 milligrams per kilogram bodyweight per day in accordance with paragraph (a)(1) of this section.

(6) Information on the environmental impact that would result from the proposed use of the substance. The request
should contain either a claim for categorical exclusion as specified in § 25.32 of this chapter or an environmental assessment as specified in § 25.40 of this chapter.

(d) Data to be reviewed under this section shall be submitted to the Food and Drug Administration’s Office of Premarket Approval (HFS-200), 200 C St. S.W., Washington, DC 20204.

(e) The Food and Drug Administration will inform the requestor by letter whether the specific food-contact application is exempt from regulation as a food additive or not. Although a substance that migrates to food at a level that results in a dietary concentration at or below the threshold of regulation will not be the subject of a regulation published in the Federal Register and will not appear in the Code of Federal Regulations, the Food and Drug Administration will maintain a list of substances exempted from regulation as food additives under this section on display at the Dockets Management Branch. This list will include the name of the company that made the request, the chemical name of the substance, the specific use for which it has received an exemption from regulation as a food additive, and any appropriate limitations on its use. The list will not include any trade names. This list will enable interested persons to see the types of uses of food-contact materials being exempted under the regulation. Interested persons may also obtain a copy of the list of exempted substances by contacting the Food and Drug Administration’s Office of Premarket Approval (HFS-200), 200 C St. S.W., Washington, DC 20204. For actions requiring an environmental assessment, the agency’s finding of no significant impact and the evidence supporting that finding, contained in the petitioner’s environmental assessment, also will be available for public inspection at the Dockets Management Branch in accordance with § 25.51(b)(2) of this chapter. Requests for copies of releasable information contained in submissions requesting exemptions from the food additive regulations will be handled in accordance with the Food and Drug Administration’s Freedom of Information Act procedures, as described in part 20 of this chapter. In particular, data and information that fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure in accordance with § 20.61(c) of this chapter.

(f) If the request for an exemption from regulation as a food additive is not granted, the requestor may submit a petition to the Food and Drug Administration for reconsideration of the decision in accordance with the provisions of § 10.33 of this chapter.

(g) If the Food and Drug Administration receives significant new information that raises questions about the dietary concentration or the safety of a substance that the agency has exempted from regulation, the Food and Drug Administration may reevaluate the substance. If the Food and Drug Administration tentatively concludes that the information that is available about the substance no longer supports an exemption for the use of the food-contact material from the food additive regulations, the agency will notify any persons that requested an exemption for the use of the substance of its tentative decision. The requestors will be given an opportunity to show why the use of the substance should not be regulated under the food additive provisions of the act. If the requestors fail to adequately respond to the new evidence, the agency will notify them that further use of the substance in question for the particular use will require a food additive regulation. This notification will be placed on public display at the Dockets Management Branch as part of the file of uses of substances exempted from regulation as food additives. The Food and Drug Administration recognizes that manufacturers other than those that actually made a request for exemption may also be using exempted substances in food-contact articles under conditions of use (e.g., use levels, temperature, type of food contacted, etc.) that are similar to those for which the exemption was issued. Because only requestors will be notified as part of the revocation process described in this section, the Food and Drug Administration plans to notify other manufacturers by means of a...
§ 170.45 Fluorine-containing compounds.

The Commissioner of Food and Drugs has concluded that it is in the interest of the public health to limit the addition of fluorine compounds to foods (a) to that resulting from the fluoridation of public water supplies as stated in § 250.203 of this chapter, (b) to that resulting from the fluoridation of bottled water within the limitation established in § 103.35(d) of this chapter, and (c) to that authorized by regulations (40 CFR part 180) under section 408 of the Act.

§ 170.50 Glycine (aminoacetic acid) in food for human consumption.

(a) Heretofore, the Food and Drug Administration has expressed the opinion in trade correspondence that glycine is generally recognized as safe for certain technical effects in human food when used in accordance with good manufacturing practice; however:

(1) Reports in scientific literature indicate that adverse effects were found in cases where high levels of glycine were administered in diets of experimental animals.

(2) Current usage information indicates that the daily dietary intake of glycine by humans may be substantially increasing due to changing use patterns in food technology. Therefore, the Food and Drug Administration no longer regards glycine and its salts as generally recognized as safe for use in human food and all outstanding letters expressing sanction for such use are rescinded.

(b) The Commissioner of Food and Drugs concludes that by May 8, 1971, manufacturers:

(1) Shall reformulate food products for human use to eliminate added glycine and its salts; or

(2) Shall bring such products into compliance with an authorizing food additive regulation. A food additive petition supported by toxicity data is required to show that any proposed level of glycine or its salts added to foods for human consumption will be safe.

(c) The status of glycine as generally recognized as safe for use in animal feed, as prescribed in § 582.5049 of this chapter, remains unchanged because the additive is considered an essential nutrient in certain animal feeds and is safe for such use under conditions of good feeding practice.

§ 170.60 Nitrites and/or nitrates in curing premixes.

(a) Nitrites and/or nitrates are food additives when combined in curing premixes with spices and/or other flavoring or seasoning ingredients that contain or constitute a source of secondary or tertiary amines, including but not limited to essential oils, disodium inosinate, disodium guanylate, hydrolysates of animal or plant origin (such as hydrolyzed vegetable protein), oleoresins of spices, soy products, and spice extractives. Such food additives may be used only after the establishment of an authorizing food additive regulation. A food additive petition submitted pursuant to §§ 171.1 and 171.100 of this chapter, supported by data demonstrating that nitrosamines are not formed in curing premixes containing such food additives, is required to establish safety.

(b) Nitrites and/or nitrates, when packaged separately from flavoring and seasoning in curing premixes, may
Food and Drug Administration, HHS

continue to be used under prior sanctions in the commercial curing of meat and meat products and poultry products and in accordance with the provisions of §§172.170 and 172.175 of this chapter that apply to meat curing preparations for the home curing of meat and meat products, including poultry and wild game. To assure safe use of such ingredients the labeling of the premixes shall bear instructions to the user that such separately packaged ingredients are not to be combined until just prior to use. Encapsulating or coating some or all of the ingredients does not constitute separate packaging.

PART 171—FOOD ADDITIVE PETITIONS

Subpart A—General Provisions

Sec.
171.1 Petitions.
171.6 Amendment of petition.
171.7 Withdrawal of petition without prejudice.
171.8 Threshold of regulation for substances used in food-contact articles.

Subpart B—Administrative Actions on Applications

171.100 Regulation based on petition.
171.102 Effective date of regulation.
171.110 Procedure for objections and hearings.
171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

SOURCE: 42 FR 14489, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 171.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the Act shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's post office address to which published notices or orders issued or objec tions filed pursuant to section 409 of the Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

<table>
<thead>
<tr>
<th>Name of petitioner</th>
<th>Post-office address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of food additive and proposed use</td>
<td></td>
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</tbody>
</table>

Petitions Control Branch
Food and Drug Administration
Department of Health and Human Services
Washington, DC 20204.

DEAR SIRS:
The undersigned, submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to

(Name of the food additive and proposed use)

Attached hereto, in triplicate, and constituting a part of this petition, are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities. Where such information is not available, a statement as to the reasons why it is not should be submitted.

When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect