

## SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION (CONTINUED)

### 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.

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(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.* Use of a substance in a food contact article (e.g., food-packaging or food-processing equipment) whereby the substance migrates, or may reasonably be expected to migrate, into food at such levels that the use has been exempted from regulation as a food additive under §170.39, and food contact substances used in accordance with a notification submitted under section 409(h) of the act that is effective.

(3) A *food contact substance* is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

(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 the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

(2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

(j) The term *nonperishable processed food* means any processed food not subject to rapid decay or deterioration that would render it unfit for consumption. Examples are flour, sugar, cereals, packaged cookies, and crackers. Not included are hermetically sealed foods or manufactured dairy products and other processed foods requiring refrigeration.

(k) *General recognition of safety* shall be in accordance with §170.30.

(l) *Prior sanction* means an explicit approval granted with respect to use of a substance in food prior to September

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6, 1958, by the Food and Drug Administration or the United States Department of Agriculture pursuant to the Federal Food, Drug, and Cosmetic Act, the Poultry Products Inspection Act, or the Meat Inspection Act.

(m) *Food* includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

(n) The following general food categories are established to group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients. Individual food products will be included within these categories according to the detailed classifications lists contained in Exhibit 33B 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 at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(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, processed, spread, dip, and miscellaneous cheeses.

(6) Chewing 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, frozen multicourse meals, and spreads containing fish, shellfish, and other aquatic animals, but not fresh fish.

(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,

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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, con-

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centrates, 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.

(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.

(o) 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 at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal-register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal-register/code_of_federal_regulations/ibr_locations.html).

(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.

(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, clouding 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

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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 bodying 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.

[42 FR 14483, Mar. 15, 1977, as amended at 47 FR 11835, Mar. 19, 1982; 53 FR 16546, May 10, 1988; 54 FR 24896, June 12, 1989; 60 FR 36595, July 17, 1995; 67 FR 35729, May 21, 2002; 81 FR 55047, Aug. 17, 2016]

### § 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 additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.

(d) Because of the time span involved, copies of many of the letters in which the Food and Drug Administration has expressed an informal opinion concerning the status of such articles may no longer be in the file of the Food and Drug Administration. In the absence of information concerning the names and uses made of all the articles referred to in such letters, their safety of use cannot be reexamined. For this reason all food additive status opinions of the kind described in paragraph (c) of this section given by the Food and Drug Administration are hereby revoked.

(e) The prior opinions of the kind described in paragraph (c) of this section will be replaced by qualified and current opinions if the recipient of each such letter forwards a copy of each to the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, along with a copy of his letter of inquiry, on or before July 23, 1970.

(f) This section does not apply to food additive status opinion letters pertaining to articles that were considered by the Food and Drug Administration

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to be food additives nor to articles included in regulations in parts 170 through 189 of this chapter if the articles are used in accordance with the requirements of such regulations.

[42 FR 14483, Mar. 15, 1977, as amended at 54 FR 24896, June 12, 1989; 81 FR 49896, July 29, 2016]

### § 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.

[42 FR 14486, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

### § 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:

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

Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

(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.

[42 FR 14483, Mar. 15, 1977, as amended at 43 FR 60021, Dec. 22, 1978]

## § 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 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.

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(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.

## § 170.19 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 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 experimen-

tation 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  $\frac{1}{100}$ th 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 throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use (see § 170.3(i)).

(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. General recognition of safety through scientific procedures shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

(c)(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be achieved without the quantity or quality of scientific procedures required for approval of a food additive. 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

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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 substance is safe under the conditions of its intended use within the meaning of section 201(u) of the Federal Food, Drug, and Cosmetic Act (see also §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; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in the United States. A person who concludes that a use of a substance is GRAS through experience based on its common use in food outside of the United States should notify FDA of that view in accordance with subpart E of this part.

(d) The food ingredients listed as GRAS in part 182 of this chapter or affirmed as GRAS in part 184 or part 186 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 part 186 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 based on the view that they are GRAS under the conditions of their intended use or subject to a prior sanction. All affirmations of GRAS status or determinations of 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 part 186 of this chapter.

(f) [Reserved]

(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 part 186 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 part 186 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 at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/](http://www.archives.gov/federal_register/)

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(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 part 186 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 part 186 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 part 186 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 to the GRAS status of a food ingredient in parts 182, 184, or 186 of this

chapter shall be accomplished pursuant to §170.38.

[42 FR 14483, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984; 53 FR 16546, May 10, 1988; 81 FR 55047, Aug. 17, 2016]

### **§ 170.35 Affirmation of generally recognized as safe (GRAS) status.**

(a) The Commissioner, on his own initiative, may affirm that a substance that directly or indirectly becomes a component of food is GRAS under the conditions of its intended use.

(b)(1) If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS under the conditions of its intended use, he will place all of the data and information on which he relies on public file in the office of the Dockets Management Staff 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 Staff. Copies of all comments received shall be made available for examination in the Dockets Management Staff's office.

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS under the conditions of its intended use as described in §170.30, he will publish a notice in the FEDERAL REGISTER listing the GRAS conditions of use of the substance in 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 a substance is GRAS under the conditions of its intended use and that it should be considered a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act, he shall publish a notice thereof in the

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FEDERAL REGISTER in accordance with § 170.38.

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

[42 FR 14488, Mar. 15, 1977, as amended at 50 FR 7492, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 53 FR 16547, May 10, 1988; 62 FR 40599, July 29, 1997; 65 FR 51762, Aug. 25, 2000; 81 FR 55048, Aug. 17, 2016; 88 FR 17718, Mar. 24, 2023]

### § 170.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 170.35(b)(4), publish a notice in the FEDERAL REGISTER determining that a substance is not GRAS under the conditions of its intended use and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may issue a notice in the FEDERAL REGISTER proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the Act. Any petition shall include all relevant data and information of the type described in § 171.130(b). The Commissioner will place all of the data and information on which he relies on public file in the office of the Dockets Management Staff and will include in the FEDERAL REGISTER notice the name of the substance, its known uses, and a summary of the basis for the determination.

(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 Staff. Copies of all comments shall be made available for examination in the Dockets Management Staff's office.

(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

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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 will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice 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 proposal.

[42 FR 14488, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 54 FR 24896, June 12, 1989; 81 FR 55048, Aug. 17, 2016; 88 FR 17718, Mar. 24, 2023]

### § 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 TD<sub>50</sub> 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 TD<sub>50</sub>, 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 TD<sub>50</sub> value has been reported in the scientific literature for a substance, the Food and Drug Administration will use the lowest appropriate TD<sub>50</sub> 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 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 (time/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.

(iv) In cases where there is no detectable migration into food or food simulants, or when no residual level of a substance is detected in the food-contact article by a suitable analytical method, the Food and Drug Administration will, for the purposes of estimating the dietary concentration, consider the validated detection limit of the method used to analyze for the substance.

(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 Food Additive Safety (HFS-200), 5001 Campus Dr., College Park, MD 20740.

(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 Staff. 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 Food Additive Safety (HFS-200), 5001 Campus Dr., College Park, MD 20740. 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 Staff 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

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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 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 Staff 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 notice published in the FEDERAL REGISTER of its decision to revoke an exemption issued for a specific use of a substance in a food contact article.

(h) Guidance documents to assist requestors in the preparation of submissions seeking exemptions from the food additive regulations are available from the Food and Drug Administration's Office of Food Additive Safety (HFS-200), 5001 Campus Dr., College Park,

MD 20740. Interested persons are encouraged to obtain specific guidance from the Food and Drug Administration on the appropriate protocols to be used for obtaining migration data, on the validation of the analytical methods used to quantify migration levels, on the procedures used to relate migration data to dietary exposures, and on any other issue not specifically covered in the Food and Drug Administration's guidance documents.

[60 FR 36595, July 17, 1995, as amended at 62 FR 40599, July 29, 1997; 65 FR 56479, Sept. 19, 2000; 81 FR 49896, July 29, 2016; 88 FR 17718, Mar. 24, 2023]

### Subpart C—Specific Administrative Rulings and Decisions

#### § 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, (b) to that resulting from the fluoridation of bottled water within the limitation established in §165.110(d) of this chapter, and (c) to that authorized by regulations (40 CFR part 180) under section 408 of the Act.

[42 FR 14483, Mar. 15, 1977, as amended at 72 FR 10357 Mar. 8, 2007]

#### § 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

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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 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

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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.

## Subpart D—Premarket Notifications

SOURCE: 67 FR 35729, May 21, 2002, unless otherwise noted.

## § 170.100 Submission of a premarket notification for a food contact substance (FCN) to the Food and Drug Administration (FDA).

(a) An FCN is effective for the food contact substance manufactured or prepared by the manufacturer or supplier identified in the FCN submission. If another manufacturer or supplier wishes to market the same food contact substance for the same use, that manufacturer or supplier must also submit an FCN to FDA.

(1) An FCN must contain all of the information described in §170.101.

(2) An FCN may incorporate by reference any information in FDA's files provided that the manufacturer or supplier is authorized to reference the information. The FCN must include information establishing that the manufacturer or supplier is authorized to reference information in FDA's files.

(3) Any material submitted in or referenced by an FCN that is in a foreign language must be accompanied by an English translation verified to be complete and accurate.

(b) FDA may choose not to accept an FCN for either of the following:

(1) A use of a food contact substance that is the subject of a regulation in parts 173 through 189 of this chapter; or

(2) A use of a food contact substance that is the subject of an exemption under the threshold of regulation process described in §170.39.

(c) A petition must be submitted under §171.1 of this chapter to authorize the safe use of a food contact substance in either of the following circumstances, unless FDA agrees to accept an FCN for the proposed use.



(1) The use of the food contact substance increases the cumulative dietary concentration to a certain level. For a substance that is a biocide (e.g., it is intended to exert microbial toxicity), this level is equal to or greater than 200 parts per billion in the daily diet (0.6 milligram (mg)/person/day). For a substance that is not a biocide, this level is equal to or greater than 1 part per million in the daily diet (3 mg/person/day); or

(2) There exists a bioassay on the food contact substance, FDA has not reviewed the bioassay, and the bioassay is not clearly negative for carcinogenic effects.

(d) A manufacturer or supplier for which a notification is effective must keep a current address on file with FDA.

(1) The current address may be either the manufacturer's (or supplier's) address or the address of the manufacturer's (or supplier's) agent.

(2) FDA will deliver correspondence to the manufacturer's or supplier's current address.

**§ 170.101 Information in a premarket notification for a food contact substance (FCN).**

An FCN must contain the following:

(a) A comprehensive discussion of the basis for the manufacturer's or supplier's determination that the use of the food contact substance is safe. This discussion must:

(1) Discuss all information and data submitted in the notification; and

(2) Address any information and data that may appear to be inconsistent with the determination that the proposed use of the food contact substance is safe.

(b) All data and other information that form the basis of the determination that the food contact substance is safe under the intended conditions of use. Data must include primary biological data and chemical data.

(c) A good laboratory practice statement for each nonclinical laboratory study, as defined under § 58.3(d) of this chapter, that is submitted as part of the FCN, in the form of either:

(1) A signed statement that the study was conducted in compliance with the

good laboratory practice regulations under part 58 of this chapter; or

(2) A brief signed statement listing the reason(s) that the study was not conducted in compliance with part 58 of this chapter.

(3) Data from any study conducted after 1978 but not conducted in compliance with part 58 of this chapter must be validated by an independent third party prior to submission to the Food and Drug Administration (FDA), and the report and signed certification of the validating party must be submitted as part of the notification.

(d) Information to address FDA's responsibility under the National Environmental Policy Act, in the form of either:

(1) A claim of categorical exclusion under § 25.30 or § 25.32 of this chapter; or

(2) An environmental assessment complying with § 25.40 of this chapter.

(e) A completed and signed FDA Form No. 3480.

**§ 170.102 Confidentiality of information in a premarket notification for a food contact substance (FCN).**

(a) During the 120-day period of the Food and Drug Administration (FDA) review of an FCN, FDA will not disclose publicly any information in that FCN.

(b) FDA will not disclose publicly the information in an FCN that is withdrawn prior to the completion of FDA's review.

(c) Once FDA completes its review of an FCN, the agency will make its conclusion about the FCN publicly available. For example, if FDA objects to a notification 90 days after the date of receipt, the agency would make available its objection at that time.

(d) By submitting an FCN to FDA, the manufacturer or supplier waives any claim to confidentiality of the information required to adequately describe the food contact substance and the intended conditions of use that are the subject of that FCN.

(e) The following data and information in an FCN are available for public disclosure, unless extraordinary circumstances are shown, on the 121st day after receipt of the notification by

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FDA, except that no data or information are available for public disclosure if the FCN is withdrawn under § 170.103.

(1) All safety and functionality data and information submitted with or incorporated by reference into the notification. Safety and functionality data include all studies and tests of a food contact substance on animals and humans and all studies and tests on a food contact substance for establishing identity, stability, purity, potency, performance, and usefulness.

(2) A protocol for a test or study, unless it is exempt from disclosure under § 20.61 of this chapter.

(3) A list of all ingredients contained in a food contact substance, excluding information that is exempt from disclosure under § 20.61 of this chapter. Where applicable, an ingredient list will be identified as incomplete.

(4) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is exempt from disclosure under § 20.61 of this chapter.

(5) All correspondence and written summaries of oral discussions relating to the notification, except information that is exempt for disclosure under § 20.61 of this chapter.

(6) All other information not subject to an exemption from disclosure under subpart D of part 20 of this chapter.

### **§ 170.103 Withdrawal without prejudice of a premarket notification for a food contact substance (FCN).**

A manufacturer or supplier may withdraw an FCN without prejudice to a future submission to the Food and Drug Administration (FDA) if FDA has not completed review of the FCN. For the purpose of this section, FDA's review is completed when FDA has allowed 120 days to pass without objecting to the FCN or FDA has issued an objection letter.

### **§ 170.104 Action on a premarket notification for a food contact substance (FCN).**

(a) If the Food and Drug Administration (FDA) does not object to an FCN within the 120-day period for FDA review, the FCN becomes effective.

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(b) If an FCN is complete when received, the 120-day review period begins on the date FDA receives the FCN.

(1) If any element required under § 170.101 is missing from an FCN, then FDA will not accept that FCN and FDA will send an FCN nonacceptance letter to the manufacturer or supplier. If the manufacturer or supplier submits the missing information before FDA sends an FCN nonacceptance letter, the 120-day review period begins on the date of receipt of the missing information.

(2) If FDA accepts an FCN, then FDA will acknowledge in writing its receipt of that FCN.

(c) Objection to an FCN:

(1) If FDA objects to an FCN, then FDA will send an FCN objection letter. The date of the letter will be the date of FDA's objection for purposes of section 409(h)(2)(A) of the act.

(2) If FDA objects to an FCN within the 120-day period for FDA review, the FCN will not become effective.

(3) FDA may object to an FCN if any part of FDA's 120-day review occurs during a period when this program is not funded as required in section 409(h)(5) of the act.

(d) If FDA and a manufacturer or supplier agree that the notifier may submit a food additive petition proposing the approval of the food contact substance for the use in the manufacturer's or supplier's FCN, FDA will consider that FCN to be withdrawn by the manufacturer or supplier on the date the petition is received by FDA.

### **§ 170.105 The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (FCN) is no longer effective.**

(a) If data or other information available to FDA, including data not submitted by the manufacturer or supplier, demonstrate that the intended use of the food contact substance is no longer safe, FDA may determine that the authorizing FCN is no longer effective.

(b) If FDA determines that an FCN is no longer effective, FDA will inform the manufacturer or supplier in writing of the basis for that determination. FDA will give the manufacturer or supplier an opportunity to show why the FCN should continue to be effective.

and will specify the time that the manufacturer or supplier will have to respond.

(c) If the manufacturer or supplier fails to respond adequately to the safety concerns regarding the notified use, FDA will publish a notice of its determination that the FCN is no longer effective. FDA will publish this notice in the FEDERAL REGISTER, stating that a detailed summary of the basis for FDA's determination that the FCN is no longer effective has been placed on public display and that copies are available upon request. The date that the notice publishes in the FEDERAL REGISTER is the date on which the notification is no longer effective.

(d) FDA's determination that an FCN is no longer effective is final agency action subject to judicial review.

#### **§ 170.106 Notification for a food contact substance formulation (NFCSF).**

(a) In order for the Food and Drug Administration (FDA) to accept an NFCSF, any food additive that is a component of the formulation must be authorized for its intended use in that NFCSF.

(b) FDA may publish a notice in the FEDERAL REGISTER stating that the agency has insufficient resources to review NFCSFs. From the date that this notice publishes in the FEDERAL REGISTER, FDA will no longer accept NFCSFs.

(c) An NFCSF must contain the following:

(1) A completed and signed FDA Form No. 3479; and

(2) Any additional documentation required to establish that each component of the formulation already may be marketed legally for its intended use.

### **Subpart E—Generally Recognized as Safe (GRAS) Notice**

SOURCE: 81 FR 55048, Aug. 17, 2016, unless otherwise noted.

#### **§ 170.203 Definitions.**

The definitions and interpretations of terms in §170.3 apply to such terms when used in this subpart. The following definitions also apply:

*Amendment* means any data and information that you submit regarding a filed GRAS notice before we respond to your notice by letter in accordance with §170.265(b)(1) or cease to evaluate your notice in accordance with §170.265(b)(3).

*GRAS* means generally recognized as safe.

*GRAS notice* means a submission that informs us of your view that a substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the substance is GRAS under the conditions of its intended use in accordance with §170.30.

*Notified substance* means the substance that is the subject of your GRAS notice.

*Notifier* means the person (e.g., an individual, partnership, corporation, association, or other legal entity) who is responsible for the GRAS notice, even if another person (such as an attorney, agent, or qualified expert) prepares or submits the notice or provides an opinion about the basis for a conclusion of GRAS status.

*Qualified expert* means an individual who is qualified by scientific training and experience to evaluate the safety of substances under the conditions of their intended use in food.

*Supplement* means any data and information that you submit regarding a filed GRAS notice after we respond to your notice by letter in accordance with §170.265(b)(1) or cease to evaluate your notice in accordance with §170.265(b)(3).

*We, our, and us* refer to the United States Food and Drug Administration (FDA).

*You and your* refer to a notifier.

#### **§ 170.205 Opportunity to submit a GRAS notice.**

Any person may notify FDA of a view that a substance is not subject to the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use.

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### § 170.210 How to send your GRAS notice to FDA.

(a) Send your GRAS notice to the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

(b) When you submit your GRAS notice, you may do so either in an electronic format that is accessible for our evaluation or on paper. If you send your GRAS notice on paper, a single paper copy is sufficient.

### § 170.215 Incorporation into a GRAS notice.

You may incorporate into your GRAS notice either specifically identified data and information that you previously submitted to the Center for Food Safety and Applied Nutrition (CFSAN), or specifically identified publicly available data and information submitted by another party, when such data and information remain in CFSAN's records, such as data and information contained in a previous GRAS notice or a food additive petition.

### § 170.220 General requirements applicable to a GRAS notice.

(a) A GRAS notice has seven parts as required by §§ 170.225 through 170.255. You must submit the data and information specified in each of these parts on separate pages or sets of pages.

(b) You must include each of the seven parts in your GRAS notice. If you do not include a part, you must include with your GRAS notice an explanation of why that part does not apply to your GRAS notice.

### § 170.225 Part 1 of a GRAS notice: Signed statements and certification.

(a) Part 1 of your GRAS notice must be dated and signed by a responsible official of your organization, or by your attorney or agent.

(b) Except as required by paragraph (c)(8) of this section, you must not include any information that is trade secret or confidential commercial information in Part 1 of your GRAS notice.

(c) In Part 1 of your GRAS notice, you must:

(1) Inform us that you are submitting a GRAS notice in accordance with this subpart;

(2) Provide the name and address of your organization;

(3) Provide the name of the notified substance, using an appropriately descriptive term;

(4) Describe the intended conditions of use of the notified substance, including the foods in which the substance will be used, the levels of use in such foods, and the purposes for which the substance will be used, including, when appropriate, a description of a subpopulation expected to consume the notified substance;

(5) Inform us of the statutory basis for your conclusion of GRAS status (*i.e.*, through scientific procedures in accordance with § 170.30(a) and (b) or through experience based on common use in food in accordance with § 170.30(a) and (c));

(6) State your view that the notified substance is not subject to the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the notified substance is GRAS under the conditions of its intended use;

(7) State that, if we ask to see the data and information that are the basis for your conclusion of GRAS status, either during or after our evaluation of your notice, you will:

(i) Agree to make the data and information available to us; and

(ii) Agree to both of the following procedures for making the data and information available to us:

(A) Upon our request, you will allow us to review and copy the data and information during customary business hours at the address you specify for where these data and information will be available to us; and

(B) Upon our request, you will provide us with a complete copy of the data and information either in an electronic format that is accessible for our evaluation or on paper;

(8) State your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552 (*e.g.*, as trade secret or as commercial

or financial information that is privileged or confidential).

(9) Certify that, to the best of your knowledge, your GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to you and pertinent to the evaluation of the safety and GRAS status of the use of the substance;

(10) State both the name and position or title of the person who signs the GRAS notice; and

(11) When applicable, state as required by § 170.270 whether you:

(i) Authorize us to send any trade secrets to the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture; or

(ii) Ask us to exclude any trade secrets from the copy of the GRAS notice that we will send to FSIS.

**§ 170.230 Part 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect.**

In Part 2 of your GRAS notice, you must include:

(a) Scientific data and information that identifies the notified substance.

(1) Examples of appropriate data and information include the chemical name, applicable registry numbers (such as a Chemical Abstracts Service (CAS) registry number or an Enzyme Commission (EC) number), empirical formula, structural formula, quantitative composition, and characteristic properties.

(2) When the source of a notified substance is a biological material, you must include data and information sufficient to identify:

(i) The taxonomic source (*e.g.*, genus, species) including, as applicable, data and information at the sub-species level (*e.g.*, variety, strain);

(ii) The part of any plant or animal used as the source; and

(iii) Any known toxicants that could be in the source;

(b) A description of the method of manufacture of the notified substance in sufficient detail to evaluate the safety of the notified substance as manufactured;

(c) Specifications for food-grade material; and

(d) When necessary to demonstrate safety, relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect.

**§ 170.235 Part 3 of a GRAS notice: Dietary exposure.**

In part 3 of your GRAS notice, you must provide data and information about dietary exposure (*i.e.*, the amount of relevant substances that consumers are likely to eat or drink as part of a total diet), regardless of whether your conclusion of GRAS status is through scientific procedures or through experience based on common use in food, as follows:

(a) You must provide an estimate of dietary exposure to the notified substance that includes exposure from its intended use and all sources in the diet; and

(b) When applicable, you must provide an estimate of dietary exposure to any other substance that is expected to be formed in or on food because of the use of the notified substance (*e.g.*, hydrolytic products or reaction products);

(c) When applicable, you must provide an estimate of dietary exposure to any other substance that is present with the notified substance either naturally or due to its manufacture (*e.g.*, contaminants or by-products);

(d) You must describe the source of any food consumption data that you use to estimate dietary exposure in accordance with paragraphs (a) through (c) of this section; and

(e) You must explain any assumptions you made to estimate dietary exposure in accordance with paragraphs (a) through (c) of this section.

**§ 170.240 Part 4 of a GRAS notice: Self-limiting levels of use.**

In circumstances where the amount of the notified substance that can be added to food is limited because food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical, in Part 4 of your GRAS

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notice you must include data and information on such self-limiting levels of use.

### **§ 170.245 Part 5 of a GRAS notice: Experience based on common use in food before 1958.**

If the statutory basis for your conclusion of GRAS status is through experience based on common use in food, in Part 5 of your GRAS notice you must include evidence of a substantial history of consumption of the notified substance for food use by a significant number of consumers prior to January 1, 1958.

### **§ 170.250 Part 6 of a GRAS notice: Narrative.**

In Part 6 of your GRAS notice, you must include a narrative that provides the basis for your conclusion of GRAS status, in which:

(a)(1) You must explain why the data and information in your notice provide a basis for your view that the notified substance is safe under the conditions of its intended use. In your explanation, you must address the safety of the notified substance, considering all dietary sources and taking into account any chemically or pharmacologically related substances in such diet;

(2) In your explanation, you must identify what specific data and information that you discuss in accordance with paragraph (a)(1) of this section are generally available, and what specific data and information that you discuss in accordance with paragraph (a)(1) of this section are not generally available, by providing citations to the list of data and information that you include in Part 7 of your GRAS notice in accordance with § 170.255;

(b) You must explain how the generally available data and information that you rely on to establish safety in accordance with paragraph (a) of this section provide a basis for your conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use;

(c) You must either:

(1) Identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status, re-

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gardless of whether those data and information are generally available; or

(2) State that you have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status;

(d) If you view any of the data and information in your notice as exempt from disclosure under the Freedom of Information Act, you must identify the specific data and information; and

(e) For non-public, safety-related data and information considered in reaching a conclusion of GRAS status, you must explain how there could be a basis for a conclusion of GRAS status if qualified experts do not have access to such data and information.

### **§ 170.255 Part 7 of a GRAS notice: List of supporting data and information in your GRAS notice.**

(a) In part 7 of your GRAS notice, you must include a list of all of the data and information that you discuss in Part 6 of your GRAS notice to provide a basis for your view that the notified substance is safe under the conditions of its intended use as described in accordance with § 170.250(a)(1).

(b) You must specify which data and information that you list in accordance with paragraph (a) of this section are generally available, and which data and information are not generally available.

### **§ 170.260 Steps you may take before FDA responds to your GRAS notice.**

(a) You may submit a timely amendment to your filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to your notice by letter in accordance with § 170.265(b)(1) or cease to evaluate your notice in accordance with § 170.265(b)(3).

(b) At any time before we respond to your GRAS notice in accordance with § 170.265(b)(1), you may request in writing that we cease to evaluate your GRAS notice. Your request does not preclude you from submitting a future GRAS notice in accordance with this subpart with respect to the notified substance.

**§ 170.265 What FDA will do with a GRAS notice.**

(a)(1) We will conduct an initial evaluation of your submission to determine whether to file it as a GRAS notice for evaluation of your view that the notified substance is GRAS under the conditions of its intended use.

(2) If we file your submission as a GRAS notice, we will send you a letter that informs you of the date of filing.

(3) If we do not file your submission as a GRAS notice, we will send you a letter that informs you of that fact and provides our reasons for not filing the submission as a GRAS notice.

(4) We will consider any timely amendment that you submit to a filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to you by letter in accordance with paragraph (b)(1) of this section, if we deem that doing so is feasible within the timeframes established in paragraph (b) of this section. If we deem that considering your amendment is not feasible within the timeframes established in paragraph (b) of this section or if we have granted your request to cease to evaluate your notice, we will inform you that we are not considering your amendment.

(b)(1) Within 180 days of filing, we will respond to you by letter based on our evaluation of your notice. We may extend the 180 day timeframe by 90 days on an as needed basis.

(2) If we extend the timeframe, we will inform you in writing of the extension as soon as practicable but no later than within 180 days of filing.

(3) If you ask us to cease to evaluate your GRAS notice in accordance with § 170.260(b), we will send you a letter informing you of our decision regarding your request.

(c) If circumstances warrant, we will send you a subsequent letter about the notice.

**§ 170.270 Procedures that apply when the intended conditions of use of a notified substance include use in a product or products subject to regulation by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture.**

If the intended conditions of use of the notified substance include use in a

product or products subject to regulation by FSIS under statutes that it administers:

(a) When applicable, you must include in your GRAS notice a statement as to whether you:

(1) Authorize us to send any trade secrets to FSIS; or

(2) Ask us to exclude any trade secrets from the copy of the GRAS notice that we will send to FSIS.

(b)(1) We will forward a copy of a GRAS notice or relevant portions thereof to FSIS;

(2) We will exclude any trade secrets unless you have authorized us to do so in accordance with paragraph (a)(1) of this section; and

(c) We will ask FSIS to advise whether the intended conditions of use comply with applicable statutes and regulations, or, if not, whether the use of the substance would be permitted in products under FSIS' jurisdiction under specified conditions or restrictions.

(d) As appropriate, we will inform you of the advice we receive from FSIS in the letter we send you in accordance with § 170.265(b)(1).

**§ 170.275 Public disclosure of a GRAS notice.**

(a) The data and information in a GRAS notice (including data and information submitted in any amendment or supplement to your GRAS notice or incorporated into your GRAS notice) are:

(1) Considered a mandatory, rather than voluntary, submission for purposes of their status under the Freedom of Information Act and our public information requirements in part 20 of this chapter; and

(2) Available for public disclosure in accordance with part 20 of this chapter as of the date that we receive your GRAS notice.

(b) We will make the following readily accessible to the public:

(1) A list of filed GRAS notices, including the information described in § 170.225(c)(2) through (c)(5);

(2) The text of any letter that we issue under § 170.265(b)(1) or (c); and

(3) The text of any letter that we issue under § 170.265(b)(3) if we grant

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your request that we cease to evaluate your notice.

(c) We will disclose all remaining data and information that are not exempt from public disclosure in accordance with part 20 of this chapter.

§ 170.280 Submission of a supplement.

If circumstances warrant, you may submit a supplement to a filed GRAS notice after we respond to your notice by letter in accordance with § 170.265(b)(1) or cease to evaluate your notice in accordance with § 170.265(b)(3).

§ 170.285 Disposition of pending GRAS affirmation petitions.

Because the procedure to submit a GRAS notice is replacing the former process to submit a GRAS affirmation petition, the following will happen to a filed GRAS affirmation petition that is pending on October 17, 2016.

(a) On October 17, 2016, we will close the docket for any GRAS affirmation petition that is still pending as of October 17, 2016.

(b) Any person who submitted a GRAS affirmation petition described in this section may submit a GRAS notice as described in this subpart and request that we incorporate the GRAS affirmation petition as described in § 170.215.

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.

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

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

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Subpart A—General Provisions

§ 171.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the Federal Food, Drug, and Cosmetic Act (the act) shall be submitted in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product). 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 objections 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:

(Date)  
Name of petitioner \_\_\_\_\_  
Post-office address \_\_\_\_\_  
Date \_\_\_\_\_  
Name of food additive and proposed use \_\_\_\_\_

Office of Food Additive Safety (HFS-200),  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration, 5001  
Campus Dr., College Park, MD 20740.

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 (quadruplicate, if intended uses include use in meat, meat food product, or poultry product), and