



International Food Information Council (IFIC) Foundation
US Food and Drug Administration (FDA)

food

ingredients & colors

For centuries, ingredients have served useful functions in a variety of foods. Our ancestors used salt to preserve meats and fish, added herbs and spices to improve the flavor of foods, preserved fruit with sugar, and pickled cucumbers in a vinegar solution. Today, consumers demand and enjoy a food supply that is flavorful, nutritious, safe, convenient, colorful and affordable. Food additives and advances in technology help make that possible.

There are thousands of ingredients used to make foods. The Food and Drug Administration (FDA) maintains a list of over 3000 ingredients in its data base “Everything Added to Food in the United States”, many of which we use at home every day (e.g., sugar, baking soda, salt, vanilla, yeast, spices and colors).

Still, some consumers have concerns about additives because they may see the long, unfamiliar names and think of them as complex chemical compounds. In fact, every food we eat — whether a just-picked strawberry or a homemade cookie — is made up of chemical compounds that determine flavor, color, texture and nutrient value. All food additives are carefully regulated by federal authorities and various international organizations to ensure that foods are safe to eat and are accurately labeled.

The purpose of this brochure is to provide helpful background information about food and color additives: what they are, why they are used in foods and how they are regulated for safe use.



Why Are Food and Color Ingredients Added to Food?

Additives perform a variety of useful functions in foods that consumers often take for granted. Some additives could be eliminated if we were willing to grow our own food, harvest and grind it, spend many hours cooking and canning, or accept increased risks of food spoilage. But most consumers today rely on the many technological, aesthetic and convenient benefits that additives provide.

Following are some reasons why ingredients are added to foods:

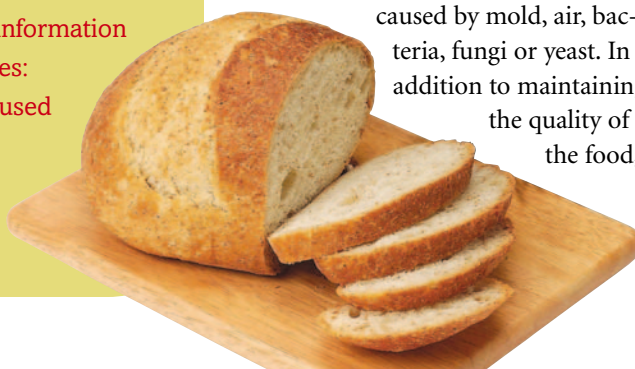
1) To Maintain or Improve Safety and Freshness:

Preservatives slow product spoilage caused by mold, air, bacteria, fungi or yeast. In addition to maintaining the quality of the food,

they help control contamination that can cause foodborne illness, including life-threatening botulism. One group of preservatives — antioxidants — prevents fats and oils and the foods containing them from becoming rancid or developing an off-flavor. They also prevent cut fresh fruits such as apples from turning brown when exposed to air.

2) To Improve or Maintain Nutritional Value:

Vitamins and minerals (and fiber) are added to many foods to make up for those lacking in a person’s diet or lost in processing, or to enhance the nutritional quality of a food. Such fortification and enrichment has helped reduce malnutrition in the U.S. and worldwide. All products containing added nutrients must be appropriately labeled.



Types of Food Ingredients

The following summary lists the types of common food ingredients, why they are used, and some examples of the names that can be found on product labels. Some additives are used for more than one purpose.

| Types of Ingredients | What They Do | Examples of Uses |
|--|--|--|
| Preservatives | Prevent food spoilage from bacteria, molds, fungi, or yeast (antimicrobials); slow or prevent changes in color, flavor, or texture and delay rancidity (antioxidants); maintain freshness | Fruit sauces and jellies, beverages, baked goods, cured meats, oils and margarines, cereals, dressings, snack foods, fruits and vegetables |
| Sweeteners | Add sweetness with or without the extra calories | Beverages, baked goods, confections, table-top sugar, substitutes, many processed foods |
| Color Additives | Offset color loss due to exposure to light, air, temperature extremes, moisture and storage conditions; correct natural variations in color; enhance colors that occur naturally; provide color to colorless and “fun” foods | Many processed foods, (candies, snack foods, margarine, cheese, soft drinks, jams/jellies, gelatins, pudding and pie fillings) |
| Flavors and Spices | Add specific flavors (natural and synthetic) | Pudding and pie fillings, gelatin dessert mixes, cake mixes, salad dressings, candies, soft drinks, ice cream, BBQ sauce |
| Flavor Enhancers | Enhance flavors already present in foods (without providing their own separate flavor) | Many processed foods |
| Fat Replacers (and components of formulations used to replace fats) | Provide expected texture and a creamy “mouth-feel” in reduced-fat foods | Baked goods, dressings, frozen desserts, confections, cake and dessert mixes, dairy products |
| Nutrients | Replace vitamins and minerals lost in processing (enrichment), add nutrients that may be lacking in the diet (fortification) | Flour, breads, cereals, rice, macaroni, margarine, salt, milk, fruit beverages, energy bars, instant breakfast drinks |
| Emulsifiers | Allow smooth mixing of ingredients, prevent separation, keep emulsified products stable, reduce stickiness, control crystallization, keep ingredients dispersed, and to help products dissolve more easily | Salad dressings, peanut butter, chocolate, margarine, frozen desserts |
| Stabilizers and Thickeners, Binders, Texturizers | Produce uniform texture, improve “mouth-feel” | Frozen desserts, dairy products, cakes, pudding and gelatin mixes, dressings, jams and jellies, sauces |
| Leavening Agents | Promote rising of baked goods | Breads and other baked goods |
| Anti-caking agents | Keep powdered foods free-flowing, prevent moisture absorption | Salt, baking powder, confectioner’s sugar |
| Humectants | Retain moisture | Shredded coconut, marshmallows, soft candies, confections |
| Yeast Nutrients | Promote growth of yeast | Breads and other baked goods |
| Dough Strengtheners and Conditioners | Produce more stable dough | Breads and other baked goods |
| Firming Agents | Maintain crispness and firmness | Processed fruits and vegetables |
| Enzyme Preparations | Modify proteins, polysaccharides and fats | Cheese, dairy products, meat |
| Gases | Serve as propellant, aerate, or create carbonation | Oil cooking spray, whipped cream, carbonated beverages |

Names Found on Product Labels

Ascorbic acid, citric acid, sodium benzoate, calcium propionate, sodium erythorbate, sodium nitrite, calcium sorbate, potassium sorbate, BHA, BHT, EDTA, tocopherols (Vitamin E)

Sucrose (sugar), glucose, fructose, sorbitol, mannitol, corn syrup, high fructose corn syrup, saccharin, aspartame, sucralose, acesulfame potassium (acesulfame-K), neotame

FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40, FD&C Yellow No. 5 (tartrazine) and No. 6, Orange B, Citrus Red No. 2, annatto extract, beta-carotene, grape skin extract, cochineal extract or carmine, paprika oleoresin, caramel color, fruit and vegetable juices, saffron (Note: Exempt color additives are not required to be declared by name on labels but may be declared simply as colorings or color added)

Natural flavoring, artificial flavor, and spices

Monosodium glutamate (MSG), hydrolyzed soy protein, autolyzed yeast extract, disodium guanylate or inosinate

Olestra, cellulose gel, carrageenan, polydextrose, modified food starch, microparticulated egg white protein, guar gum, xanthan gum, whey protein concentrate

Thiamine hydrochloride, riboflavin (Vitamin B2), niacin, niacinamide, folate or folic acid, beta carotene, potassium iodide, iron or ferrous sulfate, alpha tocopherols, ascorbic acid, Vitamin D, amino acids (L-tryptophan, L-lysine, L-leucine, L-methionine)

Soy lecithin, mono- and diglycerides, egg yolks, polysorbates, sorbitan monostearate

Gelatin, pectin, guar gum, carrageenan, xanthan gum, whey

Baking soda, monocalcium phosphate, calcium carbonate

Calcium silicate, iron ammonium citrate, silicon dioxide

Glycerin, sorbitol

Calcium sulfate, ammonium phosphate

Ammonium sulfate, azodicarbonamide, L-cysteine

Calcium chloride, calcium lactate

Enzymes, lactase, papain, rennet, chymosin

Carbon dioxide, nitrous oxide

3) Improve Taste, Texture and Appearance:

Spices, natural and artificial flavors, and sweeteners are added to enhance the taste of food. Food colors maintain or improve appearance. Emulsifiers, stabilizers and thickeners give foods the texture and consistency consumers expect. Leavening agents allow baked goods to rise during baking. Some additives help control the acidity and alkalinity of foods, while other ingredients help maintain the taste and appeal of foods with reduced fat content.

What Is a Food Additive?

In its broadest sense, a food additive is any substance added to food. Legally, the term refers to “any substance the intended use of which results or may reasonably be expected to result — directly or indirectly — in its becoming a component or otherwise affecting the characteristics of any food.” This definition includes any substance used in the production, processing, treatment, packaging, transportation or storage of food. The purpose of the legal definition, however, is to impose a pre-market approval requirement.





Therefore, this definition excludes ingredients whose use is generally recognized as safe (where government approval is not needed), those ingredients approved for use by FDA or the U.S.

Department of Agriculture prior to the food additives provisions of law, and color additives and pesticides where other legal premarket approval requirements apply.

Direct food additives are those that are added to a food for a specific purpose in that food. For example, xanthan gum — used in salad dressings, chocolate milk, bakery fillings, puddings and other foods to add texture — is a direct additive. Most direct additives are identified on the ingredient label of foods.

Indirect food additives are those that become part of the food in trace amounts due to its packaging, storage or other handling. For instance, minute amounts of packaging substances may find their way into foods during storage. Food

packaging manufacturers must prove to the U.S. Food and Drug Administration (FDA) that all materials coming in contact with food are safe before they are permitted for use in such a manner.

What Is a Color Additive?

A color additive is any dye, pigment or substance which when added or applied to a food, drug or cosmetic, or to the human body, is capable (alone or through reactions with other substances) of imparting color.

FDA is responsible for regulating all color additives to ensure that foods containing color additives are safe to eat, contain only approved ingredients and are accurately labeled.

Color additives are used in foods for many reasons: 1) to offset color loss due to exposure to light, air, temperature extremes, moisture and storage conditions; 2) to correct natural variations in color; 3) to enhance colors that occur naturally; and 4) to provide color to colorless and “fun” foods.



Without color additives, colas wouldn't be brown, margarine wouldn't be yellow and mint ice cream wouldn't be green. Color additives are now recognized as an important part of practically all processed foods we eat.

FDA's permitted colors are classified as subject to certification or **exempt from certification**, both of which are subject to rigorous safety standards prior to their approval and listing for use in foods.

- **Certified colors** are synthetically produced (or human made) and used widely because they impart an intense, uniform color, are less expensive, and blend more easily to create a variety of hues. There are nine certified color additives approved for use in the United States (e.g., FD&C Yellow No. 6. See chart for complete list.). Certified food colors generally do not add undesirable flavors to foods.
- Colors that are **exempt from certification** include pigments derived from natural sources such as vegetables, minerals or animals. Nature derived color additives are typically more expensive than certified colors and may add unintended flavors to foods. Examples of exempt colors include annatto extract (yellow), dehydrated beets (bluish-red to brown), caramel (yellow to tan), beta-carotene (yellow to orange) and grape skin extract (red, green).

How Are Additives Approved for Use in Foods?

Today, food and color additives are more strictly studied, regulated and monitored than at any other time in history. FDA has the primary legal responsibility for determining their safe use. To market a new food or color additive (or before using an additive already approved for one use in another manner not yet approved), a manufacturer or other sponsor must first petition FDA for its approval. These petitions must provide evidence that the substance is safe for the

ways in which it will be used. As a result of recent legislation, since 1999, indirect additives have been approved via a premarket notification process requiring the same data as was previously required by petition.

When evaluating the safety of a substance and whether it should be approved, FDA considers: 1) the composition and properties of the substance, 2) the amount that would typically be consumed, 3) immediate and long-term health effects, and 4) various safety factors. The evaluation determines an appropriate level of use that includes a built-in safety margin — a factor that allows for uncertainty about the levels of consumption that are expected to be harmless. In other words, the levels of use that gain approval are much lower than what would be expected to have any



adverse effect.

Because of inherent limitations of science, FDA can never be *absolutely* certain of the absence of any risk from the use of any substance. Therefore, FDA must determine — based on the best science available — if there is a *reasonable certainty of no harm* to consumers when an additive is used as proposed.

If an additive is approved, FDA issues regulations that may include the types of foods in which it can be used, the maximum amounts to be used, and how it should be identified on food labels. In 1999, procedures changed so that FDA now consults with USDA during the review process for ingredients that are proposed for use in meat and poultry products. Federal officials then monitor the extent of Americans' consumption of the new additive and results of any new research on its safety to ensure its use

continues to be within safe limits.

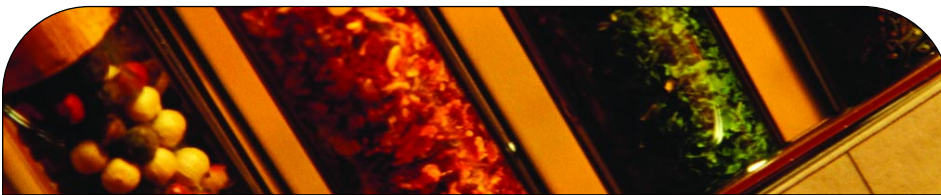
If new evidence suggests that a product already in use may be unsafe, or if consumption levels have changed enough to require another look, federal authorities may prohibit its use or conduct further studies to determine if the use can still be considered safe.

Regulations known as Good Manufacturing Practices (GMP) limit the amount of food ingredients used in foods to the amount necessary to achieve the desired effect.

Summary

Food ingredients have been used for many years to preserve, flavor, blend, thicken and color foods, and have played an important role in reducing serious nutritional deficiencies among consumers. These ingredients also help ensure the availability of flavorful, nutritious, safe, convenient, colorful and affordable foods that meet consumer expectations year-round.

Food and color additives are strictly studied, regulated and monitored. Federal regulations require evidence that each substance is safe at its intended level of use before it may be added to foods. Furthermore, all additives are subject to ongoing safety review as scientific understanding and methods of testing continue to improve. Consumers should feel safe about the foods they eat.



Under the Food Additives Amendment, two groups of ingredients were exempted from the regulation process.

GROUP I — Prior-sanctioned substances — are substances that FDA or USDA had determined safe for use in food prior to the 1958 amendment. Examples are sodium nitrite and potassium nitrite used to preserve luncheon meats.

GROUP II — GRAS (generally recognized as safe) ingredients — are those that are generally recognized by experts as safe, based on their extensive history of use in food before 1958 or based on published scientific evidence. Among the several hundred GRAS substances are salt, sugar, spices, vitamins and monosodium glutamate (MSG). Manufacturers may also request that FDA review the industry's determination of GRAS Status.

About Food and Questions & Answers Color Additives

Q How are ingredients listed on a product label?

A Food manufacturers are required to list all ingredients in the food on the label. On a product label, the ingredients are listed in order of predominance, with the ingredients used in the greatest amount first, followed in descending order by those in smaller amounts. The label must list the names of any FDA-certified color additives (e.g., FD&C Blue No. 1 or the abbreviated name, Blue 1). But some ingredients can be listed collectively as “flavors,” “spices,” “artificial flavoring,” or in the case of color

additives exempt from certification, “artificial colors”, without naming each one.

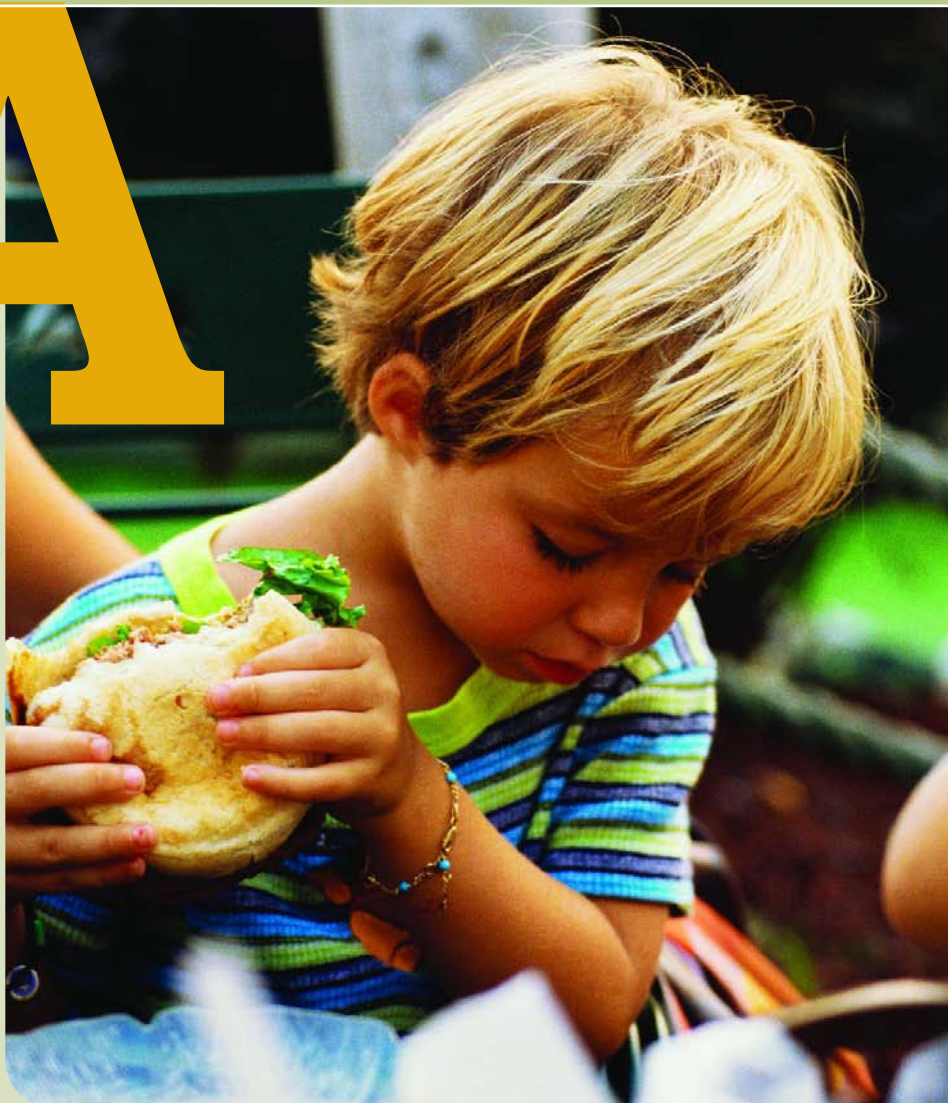
Declaration of an allergenic ingredient in a collective or single color, flavor, or

spice could be accomplished by simply naming the allergenic ingredient in the ingredient list.

Q What are dyes and lakes in color additives?

A **Certified color** additives are categorized as either dyes or lakes.

Dyes dissolve in water and are manufac-



tured as powders, granules, liquids or other special-purpose forms. They can be used in beverages, dry mixes, baked goods, confections, dairy products, pet foods and a variety of other products.

Lakes are the water insoluble form of the dye. Lakes are more stable than dyes and are ideal for coloring products containing fats and oils or items lacking sufficient moisture to dissolve dyes. Typical uses include coated tablets, cake and donut mixes, hard candies and chewing gums.

Q Do additives cause childhood hyperactivity?

A No. Although this hypothesis was popularized in the 1970's, well-controlled studies conducted since then have

produced no evidence that food additives cause hyperactivity or learning disabilities in children. A Consensus Development Panel of the National Institutes of Health concluded in 1982 that there was no scientific evidence to support the claim that additives or colorings cause hyperactivity. However, for some children with attention deficit hyperactivity disorder (ADHD) and confirmed food allergy, dietary modification has produced some improvement in behavior. The panel said that elimination diets should not be used universally to treat childhood hyperactivity, since there is no scientific evidence to predict which children may benefit. A 1997 review published in the *Journal of the American Academy of Child & Adolescent Psychiatry*

noted there is minimal evidence of efficacy and extreme difficulty inducing children and adolescents to comply with restricted diets. Thus, dietary treatment should not be recommended, except possibly with a small number of preschool children who may be sensitive to tartrazine, known commonly as FD&C Yellow No. 5. [See question below.]

Q What is the difference between natural and artificial ingredients? Is a naturally produced ingredient safer than an artificially manufactured ingredient?

A Natural ingredients are derived from natural sources (e.g., soybeans and corn provide lecithin to maintain product consistency; beets provide beet powder used as food coloring). Other ingredients are not found in nature and therefore must be synthetically produced as artificial ingredients. Also, some ingredients found in nature can be manufactured artificially and produced more economically, with greater purity and more consistent quality, than their natural counterparts. For example, vitamin C or ascorbic acid may be derived from an orange or produced in a laboratory. Food ingredients are subject to the same strict safety standards regardless of whether they are naturally or artificially derived.

Q Are certain people sensitive to FD&C Yellow No. 5 in foods?

A FD&C Yellow No. 5, is used to color beverages, dessert powders, candy, ice cream, custards and other foods. FDA's Committee on Hypersensitivity to

Food Constituents concluded in 1986 that FD&C Yellow No. 5 might cause hives in fewer than one out of 10,000 people. It also concluded that there was no evidence the color additive in food provokes asthma attacks. The law now requires Yellow No. 5 to be identified on the ingredient line. This allows the few who may be sensitive to the color to avoid it.

Q Do low-calorie sweeteners cause adverse reactions?

A No. Food safety experts generally agree there is no convincing evidence of a cause and effect relationship between these sweeteners and negative health effects in humans. The FDA has monitored consumer complaints of possible adverse reactions for more than 15 years.

For example, in carefully controlled clinical studies, aspartame has not been shown to cause adverse or allergic reactions. However, persons with a rare hereditary disease known as phenylketonuria (PKU) must control their intake of phenylalanine from all sources, including aspartame. Although aspartame contains only a small amount of phenylalanine, labels of aspartame-containing foods and beverages must include a statement advising phenylketonurics of the presence of phenylalanine.

Individuals who have concerns about possible adverse effects from food additives or other substances should contact their physicians.



Q How do they add vitamins and minerals to fortified cereals?

A Adding nutrients to a cereal can cause taste and color changes in the product. This is especially true with added minerals. Since no one wants cereal that tastes like a vitamin supplement, a variety of techniques are employed in the fortification process. In general, those nutrients that are heat stable (such as vitamins A and E and various minerals) are incorporated into the cereal itself (they're baked right in). Nutrients that are not stable to heat (such as B-vitamins) are applied directly to the cereal after all heating steps are completed. Each cereal is unique — some can handle more nutrients than others can. This is one reason why fortification levels are different across all cereals.

Q What is the role of modern technology in producing food additives?

A Many new techniques are being researched that will allow the production of additives in ways not previously possible. One approach is the use of biotechnology, which can use simple organisms to produce food additives. These additives are the same as food components found in nature. In 1990, FDA approved the first bioengineered enzyme, rennin, which traditionally had been extracted from calves' stomachs for use in making cheese.



Additional information is available from the following organizations:

Food and Drug Administration

www.fda.gov

Center for Food Safety and Applied Nutrition (CFSAN)

5100 Paint Branch Parkway
College Park, MD 20740-3835
www.cfsan.fda.gov

Color additives information

www.cfsan.fda.gov/~dms/col-toc.html
Toll free information line:
1-888-SAFEFOOD (723-3366)

U.S. Department of Agriculture

Food Safety and Inspection Service
Food Safety Education Staff
1400 Independence Ave., SW
Room 2932-S
Washington, DC 20250-3700
www.fsis.usda.gov

Food additives information

www.fsis.usda.gov/OA/pubs/additive.htm

Meat and Poultry Hotline: 1-800-535-4555;

TTY: 1-800-256-7072
Meat and Poultry Email: fsis@usda.gov

Food and Nutrition Information Center

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American Dietetic Association (ADA)

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Chicago, IL 60606
www.eatright.org
800-877-1600

The Food Allergy and Anaphylaxis Network (FAAN)

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