



The color of food is an integral part of our culture and enjoyment of life. Who would deny the mouth-watering appeal of a deep-pink strawberry ice on a hot summer day or a golden Thanksgiving turkey garnished with fresh green parsley?

Even early civilizations such as the Romans recognized that people "eat with their eyes" as well as their palates. Saffron and other spices were often used to provide a rich yellow color to various foods. Butter has been colored yellow as far back as the 1300's.

Today all food color additives are carefully regulated by federal authorities to ensure that foods are safe to eat and accurately labeled. This brochure provides helpful background information about color additives, why they are used in foods, and regulations governing their safe use in the food supply.

What is a Color Additive?

Technically, a color additive is any dye, pigment or substance that can impart color when added or applied to a food, drug, cosmetic or to the human body.

The Food and Drug Administration (FDA) is responsible for regulating all color additives used in the United States. All color additives permitted for use in foods are classified as "certifiable" or "exempt from certification" (see Table I).

Certifiable color additives are manmade, with each batch being tested by manufacturer and FDA. This "approval" process, known as color additive certification, assures the safety, quality, consistency and strength of the color additive prior to its use in foods.

There are nine certified colors approved for use in food in the United States. One example is FD&C Yellow No.6, which is used in cereals, bakery goods, snack foods and other foods.

Color additives that are exempt from certification include pigments derived from natural sources such as vegetables, minerals or animals, and man-made counterparts of natural derivatives.

For example, caramel color is produced commercially by heating sugar and other carbohydrates under strictly controlled conditions for use in sauces, gravies, soft drinks, baked goods and other foods.

Whether a color additive is certifiable or exempt from certification has no bearing on its overall safety. Both types of color additives are subject to rigorous standards of safety prior to their approval for use in foods.

Certifiable color additives are used widely because their coloring ability is more intense than most colors derived from natural products;

thus, they are often added to foods in smaller quantities. In addition, certifiable color additives are more stable, provide better color uniformity and blend together easily to provide a wide range of hues. Certifiable color additives generally do not impart undesirable flavors to foods, while color derived from foods such as beets and cranberries can produce such unintended effects.

Of nine certifiable colors approved for use in the United States, seven color additives are used in food manufacturing (see Table II). Regulations known as Good Manufacturing Practices limit the amount of color added to foods. Too much color would make foods unattractive to consumers, in addition to increasing costs. [TOP](#)

What Are Dyes and Lakes?

Certifiable color additives are available for use in food as either "dyes" or "lakes." Dyes dissolve in water and are manufactured 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. [TOP](#)

Why Are Color Additives Used In Foods?

Color is an important property of foods that adds to our enjoyment of eating. Nature teaches us early to expect certain colors in certain foods, and our future acceptance of foods is highly dependent on meeting these expectations.

Color variation in foods throughout the seasons and the effects of food processing and storage often require that manufacturers add color to certain foods to meet consumer expectations. The primary reasons of adding colors to foods include:

- To offset color loss due to exposure to light, air, extremes of temperature, moisture and storage conditions.
- To correct natural variations in color. Off-colored foods are often incorrectly associated with inferior quality. For example, some tree-ripened oranges are often sprayed with Citrus Red No.2 to correct the natural orangy-brown or mottled green color of their peels (Masking inferior quality, however, is an unacceptable use of colors.)
- To enhance colors that occur naturally but at levels weaker than those usually associated with a given food.
- To provide a colorful identity to foods that would otherwise be virtually colorless. Red colors provide a pleasant identity to strawberry ice while lime sherbet is known by its bright green color.
- To provide a colorful appearance to certain "fun foods." Many

candies and holiday treats are colored to create a festive appearance.

- To protect flavors and vitamins that may be affected by sunlight during storage.
- To provide an appealing variety of wholesome and nutritious foods that meet consumers' demands. [TOP](#)

How Are Color Additives Regulated?

In 1900, there were about 80 man-made color additives available for use in foods. At that time there were no regulations regarding the purity and uses of these dyes.

Legislation enacted since the turn of the century, however, has greatly improved food color additive safety and stimulated improvements in food color technology.

The Food and Drug Act of 1906 permitted or "listed" seven man-made color additives for use in foods. The Act also established a voluntary certification program, which was administered by the U.S. Department of Agriculture (USDA); hence man-made color additives became known as "certifiable color additives".

The Federal Food, Drug & Cosmetic (FD&C) Act of 1938 made food color additive certification mandatory and transferred the authority for its testing from USDA to FDA. To avoid confusing color additives used in food with those manufactured for other uses, three categories of certifiable color additives were created:

- Food, Drug and Cosmetic (FD&C) - Color additives with application in foods, drugs or cosmetics;
- Drug and Cosmetic (D&C) - Color additives with applications in drugs or cosmetics;
- External Drug and Cosmetic (External D&C) - Color additives with applications in externally applied drugs (e.g. ointments) and in externally applied cosmetics.

In 1960, the Color Additive Amendments to the FD&C Act placed color additives on a "provisional" list and required further testing using up-to-date procedures. One section of the amendment known as the Delaney Clause, prohibits adding to any food substance that has been shown to cause cancer in animals or man regardless of the dose. Under the amendments, color additives exempt from certification also are required to meet rigorous safety standards prior to being permitted for use in foods.

According to the Nutrition Labeling and Education Act of 1990, a certifiable color additive used in food must be listed in the ingredient statement by its common or usual name. All label printed after July 1, 1991 must comply with this requirement. [TOP](#)

How Are Color Additives Approved for Use in Foods?

To market a new color additive, a manufacturer must first petition

FDA for its approval. The petition must provide convincing evidence that the proposed color additive performs as it is intended. Animal studies using large doses of the color additive for long periods are often necessary to show that the substance would not cause harmful effects at expected levels of human consumption. Studies of the color additive in humans also may be submitted to FDA.

In deciding whether a color additive should be approved, the agency considers the composition and properties of the substance, the amount likely to be consumed, its probable long-term effects and various safety factors. Absolute safety of any substance can never be proven. Therefore, FDA must determine if there is a reasonable certainty of no harm from the color additive under its proposed conditions of use.

If the color 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. Color additives proposed for use in meat and poultry products also must receive specific authorization by USDA.

Federal officials then carefully monitor the extent of Americans' consumption of the new color additive and results of any new research on its safety.

In addition, FDA operates an Adverse Reaction Monitoring System (ARMS) to help serve as an ongoing safety check of all activities. The system monitors and investigates all complaints by individuals or their physicians that are believed to be related to food and color additives; specific foods; or vitamin and mineral supplements. The ARMS computerized database helps officials decide whether reported adverse reactions represent a real public health hazard, so that appropriate action can be taken. [TOP](#)

Additional Information About Color Additives

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

A. FDA's Advisory Committee on Hypersensitivity to Food Constituents concluded in 1986 that FD&C Yellow No.5 may cause hives in fewer than one out of 10,000 people. The committee found that there was no evidence the color additive in foods provokes asthma attacks nor that aspirin-intolerant individuals may have a cross-sensitivity to the color. As with other color additives certifiable for food use, whenever FD&C Yellow No.5 is added to foods, it is listed on the product label. This allows the small portion of people who may be sensitive to the color to avoid it.

Q. What is the status of FD&C Red No.3?

A. In 1990, FDA discontinued the provisional listing of all lake forms of FD&C Red No.3 and its dye form used in external drugs and cosmetics. The uses were terminated because one study of the color additive in male rats showed an association with thyroid tumors. In announcing the decision, FDA stated that any human risk posed by FD&C

Red No.3 was extremely small and was based less on safety concerns than the legal mandate of the Delaney Clause. FD&C Red No.3 remains permanently listed for use in food and ingested drugs, although FDA has announced its intent to propose rescinding those listings.

Q. Why are decisions sometimes changed about the safety of food color additives?

A. Since absolute safety of any substance can never be proven, decisions about the safety of color additives or other food ingredients are made on the best scientific evidence available. Because scientific knowledge is constantly evolving, federal officials often review earlier decisions to assure that the safety assessment of a food substance remains up-to-date. Any change made in previous clearances should be recognized as an assurance that the latest and best scientific knowledge is being applied to enhance the safety of the food supply.

Q. Do food color additives cause hyperactivity?

A. Although this theory was popularized in the 1970's, well-controlled studies conducted since then have produced no evidence that food color 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 colorings or other food additives cause hyperactivity. 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. [TOP](#)

Table 1. Color Additives Permitted For Direct Addition To Human Food In The United States

Certifiable Colors

FD&C Blue No.1 (Dye and Lake), FD&C Blue No.2 (Dye and Lake), FD&C Green No.3 (Dye and Lake), FD&C Red No.3 (Dye), FD&C Red No.40 (Dye and Lake), FD&C Yellow No.5 (Dye and Lake), FD&C Yellow No.6 (Dye and Lake), Orange B*, Citrus Red No.2*

Colors Exempt from Certification

Annatto extract, B-Apo-8'-carotenal*, Beta-carotene, Beet powder, Canthaxanthin, Caramel color, Carrot oil, Cochineal extract (carmine); Cottonseed flour, toasted partially defatted, cooked; Ferrous gluconate *, Fruit juice, Grape color extract*, Grape skin extract* (enocianina), Paprika, Paprika oleoresin, Riboflavin, Saffron, Titanium dioxide*, Turmeric, Turmeric oleoresin, Vegetable juice

*These food color additives are restricted to specific uses.

Table II. Color Additives Certifiable For Food Use

Name/Common Name	Hue	Common Food Uses
FD&C Blue No.1 Brilliant Blue FCF	Bright blue	Beverages, dairy products powders, jellies, confections, condiments, icings, syrups, extracts
FD&C Blue No.2 Indigotine	Royal Blue	Baked goods, cereals, snack foods, ice cream, confections, cherries
FD&C Green No.3 Fast Green FCF	Sea Green	Beverages, puddings, ice cream, sherbert, cherries, confections, baked goods, dairy products
FD&C Red No.40 Allura Red AC	Orange-red	Gelatins, puddings, dairy products, confections, beverages, condiments
FD&C Red No.3 Erythrosine	Cherry-red	Cherries in fruit cocktail and in canned fruits for salads, confections, baked goods, dairy products, snack foods
FD&C Yellow No.5 Tartrazine	Lemon Yellow	Custards, beverages, ice cream, confections, preserves, cereals
FD&C Yellow No.6 Sunset Yellow	Orange	Cereals, baked goods, snack foods, ice cream, beverages, dessert powders, confections

*Food and Drug Administration HFI 140
5600 Fishers Lane Rockville MD 20857*

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*International Food Information Council Foundation
1100 Connecticut Ave, N.W. Suite 430
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