EXTENSION

FAPC-261

Food color additives explained: Benefits, risks and regulation

October 2026

Introduction

The addition of color to foods not only enhances their visual appeal but also helps consumers readily associate products with specific flavors or characteristics, such as orange with citrus and yellow with lemon. Food color additives, also known as dyes, pigments or coloring agents, serve several important functions beyond aesthetics. They compensate for color loss caused by exposure to light, oxygen, temperature fluctuations, moisture, processing and storage conditions. In addition, they help correct natural variations in color among food products, enhance naturally occurring colors and impart color to otherwise colorless foods, thereby improving product consistency, consumer acceptance and marketability. Color also has a profound influence on consumers' sensory perception. Altering the color of a food can modify its perceived taste or flavor, while the appearance of a food strongly influences consumer assessments of freshness, flavor and overall quality, ultimately shaping expectations of product acceptability and preference (Spence, 2015).

The use of colorants in foods has a long history dating back several centuries. Natural colorants derived from vegetable and mineral sources were used in ancient civilizations to color foods, pharmaceuticals and cosmetics. Historical records indicate that wine was artificially colored as early as 300 BC. In the United States, federal oversight of food colorants began in 1881 when the U.S. Department of Agriculture's (USDA) Bureau of Chemistry initiated research on the use of color additives in foods. Butter and cheese were among the first food products authorized for artificial coloring under federal regulation (Albuquerque et al., 2021).

Regulations and approval process

The Federal Food, Drug, and Cosmetic Act (U.S. Food and Drug Administration, 2018) requires that all color additives, as well as any new uses of previously approved color additives, receive approval from the U.S. Food and Drug Administration (FDA) before they may be used in foods (U.S. Food and Drug Administration, 2026b). Any individual or organization may petition the FDA to approve a new color additive or to amend the approved uses of an existing color additive by submitting comprehensive scientific and technical information, including:

- Identity of the proposed color additive
- Physical, chemical and biological properties
- Chemical specifications
- Description of the manufacturing process
- Stability data
- Intended uses and use restrictions
- Labeling requirements
- Tolerances and limitations
- Analytical methods for verifying compliance with chemical specifications
- Analytical methods for determining the concentration of the color additive in food products
- Identification and analytical determination of substances formed in or on foods because of the use of the color additive

The FDA evaluates each petition by considering multiple factors, including the chemical composition and physicochemical properties of the additive, estimated dietary exposure, potential short- and long-term health effects, the availability of validated analytical methods to determine the additive's identity, purity and permissible levels of impurities, public comments submitted during the review process and other relevant scientific information available to the agency. Only color additives that meet the FDA's safety standards are approved for use in food products.

Following approval, the FDA continues to monitor the safety of color additives. If new scientific evidence indicates that an approved color additive may present a health risk or that consumer exposure has changed significantly, the agency may require additional safety studies, modify the approved conditions of use, suspend approval or revoke authorization altogether. Manufacturers are expected to take prompt corrective actions when safety concerns arise, including voluntary product recalls when appropriate. If voluntary compliance is not achieved, the FDA may issue warning letters, public safety alerts, seize adulterated products or pursue other enforcement actions to prevent the distribution of foods containing unapproved or unsafe color additives.

FDA-approved food color additives are classified into two categories: certified color additives, which require batch certification and color additives exempt from certification. Batch certification is primarily required for synthetic color additives because their composition must be carefully controlled to protect public health, given the potential presence of toxicologically significant impurities.

Under the batch certification program, manufacturers must submit a representative sample from every production batch to the FDA's Color Certification Branch along with a Request for Certification. Until certification has been granted, the batch may not be used in foods and must be stored separately from previously certified batches.

Upon receipt of the sample, FDA scientists evaluate its physical characteristics and conduct extensive chemical analyses to determine total color content (purity), moisture content, residual salts, unreacted intermediates, subsidiary colors (colored impurities other than the principal color), specified impurities and the concentrations of heavy metals, including lead, arsenic and mercury. The analytical results are compared with the identity and specification requirements established in the applicable listing regulation. If the batch complies with all regulatory requirements, the FDA issues a certificate authorizing its use. Owners of certified batches remain subject to periodic FDA inspections, during which agency personnel review records documenting the use of certified color additives and collect samples for independent analysis to verify continued compliance with regulatory specifications.

Food color additives requiring batch certification listed in 21 CFR Part 74 (U.S. Food and Drug Administration, 2026a) include FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40 and FD&C Yellow Nos. 5 and 6. FDA has revoked authorization for FD&C Red No. 3, and food manufacturers have until Jan. 15, 2027, to reformulate products containing it. Although these additives were historically known as coal-tar colors because they were originally derived from coal tar, modern synthetic color additives are produced primarily from petroleum- or, to a lesser extent, coal-derived chemical feedstocks. Six synthetic dyes account for the majority of food color use in the United States: FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5 and FD&C Yellow No. 6.

Color additives exempt from certification are generally obtained from natural plant, animal or mineral sources. Common examples include annatto extract (yellow to orange), dehydrated beet powder (bluish red to brown), caramel color (yellow to dark brown), β-carotene (yellow to orange) and grape skin extract (red to purple).

Unlike certifiable color additives, exempt color additives are not required to undergo FDA batch certification prior to marketing. Nevertheless, manufacturers remain responsible for ensuring compliance with applicable regulatory specifications and good manufacturing practices. On food labels, exempt color additives may generally be declared simply as "artificial color," "artificial coloring," "color added" or by their common or usual names, as permitted by FDA labeling regulations. The complete list of color additives exempt from certification is provided in 21 CFR Part 73, whereas certifiable color additives are listed in 21 CFR Part 74 (U.S. Food and Drug Administration, 2026a). Importantly, the Federal Food, Drug and Cosmetic Act does not provide a Generally Recognized as Safe (GRAS) exemption for color additives. Consequently, every color additive intended for use in foods must undergo FDA review and approval through the color additive petition process before it may be legally marketed or used.

Food colorants and health

Growing public concern regarding the potential health effects of synthetic food dyes has led to renewed regulatory scrutiny. Recently, the U.S. Department of Health and Human Services announced an initiative to phase out the use of petroleum-derived synthetic food dyes because of concerns regarding their potential adverse health effects (US Food and Drug Administration, 2025). As part of this broader transition, the FDA revoked authorization for the use of FD&C Red No. 3 in foods and ingested drugs in January 2025. Although the original compliance deadline was Jan. 15, 2027 (with certain products extending into 2028), more recent FDA communications have encouraged manufacturers to remove Red No. 3 from food products as soon as practical (U.S. Food and Drug Administration, 2025). The FDA is working with industry to eliminate six remaining commonly used certified color additives from the food supply by the end of 2027 (U.S. Food and Drug Administration, n.d.). This transition period is intended to provide the food industry sufficient time to identify, evaluate and implement suitable alternative colorants while minimizing disruption to the national food supply.

The principal concerns regarding petroleum-derived synthetic food dyes include their potential effects on human health, particularly allergenicity, carcinogenicity and possible neurobehavioral effects (Neal et al., 2026). Several studies have reported

associations between synthetic food dyes and hyperactive behavior in children (de Oliveira et al., 2024; McCann et al., 2007), an increased risk of colorectal cancer (Zand et al., 2023; Zhang et al., 2023) and a variety of allergic clinical manifestations (Feketea & Tsabouri, 2017). However, these findings should be interpreted cautiously. Many toxicological studies were conducted in laboratory animals exposed to doses substantially higher than typical human dietary intake, often over relatively short experimental periods. Furthermore, some studies evaluated complex food formulations containing multiple additives rather than isolated synthetic colorants, making it difficult to attribute the observed effects solely to food dyes (Nigg et al., 2012).

What does this mean for consumers?

For most people, consuming foods containing FDA-approved color additives under their approved conditions of use is not expected to pose a significant health risk. Nevertheless, consumers who wish to reduce their intake of synthetic food dyes should:

- Read ingredient labels carefully.
- Choose foods colored with naturally derived ingredients when available.
- Limit consumption of foods that contain multiple artificial additives.
- Emphasize a balanced diet rich in fruits, vegetables and whole grains.

Parents of children who appear to be sensitive to certain food colorants may wish to discuss dietary concerns with their healthcare provider before making significant dietary changes.

References

Albuquerque, B. R., Oliveira, M. B. P. P., Barros, L., & Ferreira, I. C. F. R. (2021). Could fruits be a reliable source of food colorants? Pros and cons of these natural additives. Critical Reviews in Food Science and Nutrition, 61(5), 805–835. https://doi.org/10.1080/10408398.2020.1746904

de Oliveira, Z. B., Silva da Costa, D. V., da Silva Dos Santos, A. C., da Silva Júnior, A. Q., de Lima Silva, A., de Santana, R. C. F., Costa, I. C. G., de Sousa Ramos, S. F., Padilla, G., & da Silva, S. K. R. (2024). Synthetic colors in food: A warning for children's health. International Journal of Environmental Research and Public Health, 21(6), 682.

Feketea, G., & Tsabouri, S. (2017). Common food colorants and allergic reactions in children: Myth or reality? Food Chemistry, 230, 578–588.

McCann, D., Barrett, A., Cooper, A., Crumpler, D., Dalen, L., Grimshaw, K., Kitchin, E., Lok, K., Porteous, L., & Prince, E. (2007). Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: A randomised, double-blinded, placebo-controlled trial. The Lancet, 370(9598), 1560–1567.

Neal, W. M., Osman, A. G., Khan, I. A., & Chittiboyina, A. G. (2026). Natural product-based colorants as substitutes for petroleum-based synthetic food dyes: Sources, chemistry, and characteristics. Food Chemistry, 501, 147561. https://doi.org/10.1016/j.foodchem.2025.147561

Nigg, J. T., Lewis, K., Edinger, T., & Falk, M. (2012). Meta-analysis of attention-deficit/hyperactivity disorder or attention-deficit/hyperactivity disorder symptoms, restriction diet, and synthetic food color additives. Journal of the American Academy of Child & Adolescent Psychiatry, 51(1), 86–97.

Spence, C. (2015). On the psychological impact of food colour. Flavour, 4(1), 21.

US Food and Drug Administration. (2025, January 15). FDA to Revoke Authorization for the Use of Red No. 3 in Food and Ingested Drugs [Constituent Update]. https://www.fda.gov/food/hfp-constituent-updates/fda-revoke-authorization-use-red-no-3-food-and-ingested-drugs

U.S. Food and Drug Administration. (2018). FD&C Act Chapter IV: Food. https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-iv-food

U.S. Food and Drug Administration. (2025). HHS, FDA to Phase Out Petroleum-Based Synthetic Dyes in Nation's Food Supply [Letter]. https://www.fda.gov/news-events/press-announcements/hhs-fda-phase-out-petroleum-based-synthetic-dyes-nations-food-supply

U.S. Food and Drug Administration. (2026a). Listing of color additives subject to certification. U.S. Food and Drug Administration. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-74

U.S. Food and Drug Administration. (2026b). Regulatory Status of Color Additives. https://hfpappexternal.fda.gov/scripts/fdcc/?set=ColorAdditives&sort=Sort_Unique_ID&order=ASC&startrow=1&type=column&search=Use-current%C2%A4VARCHAR%C2%A4foods

U.S. Food and Drug Administration. (n.d.). Tracking food industry pledges to remove petroleum based food dyes. Retrieved Sept. 18, 2026, from https://www.fda.gov/food/color-additives-information-consumers/tracking-food-industry-pledges-remove-petroleum-based-food-dyes

Zand, A., Enkhbilguun, S., Macharia, J. M., Budán, F., Gyöngyi, Z., & Varjas, T. (2023). Tartrazine Modifies the Activity of DNMT and HDAC Genes—Is This a Link between Cancer and Neurological Disorders? Nutrients, 15(13), 2946. https://doi.org/10.3390/nu15132946

Zhang, Q., Chumanevich, A. A., Nguyen, I., Chumanevich, A. A., Sartawi, N., Hogan, J., Khazan, M., Harris, Q., Massey, B., & Chatzistamou, I. (2023). The synthetic food dye, Red 40, causes DNA damage, causes colonic inflammation, and impacts the microbiome in mice. Toxicology Reports, 11, 221–232.



Nurhan Turgut Dunford
Extension Specialist for Oilseed Chemistry
Robert M. Kerr Food and Agricultural Products Center
Professor, Biosystems and Agricultural Engineering



Scan the code or visit **extension.okstate.edu/fact-sheets** for more OSU Extension fact sheets.

EDUCATION EVERYWHERE FOR EVERYONE
Division of Agricultural Sciences and Natural Resources

Oklahoma State University, as an equal opportunity employer, complies with all applicable federal and state laws regarding non-discrimination. Oklahoma State University is committed to a policy of equal opportunity for all individuals and does not discriminate based on race, religion, age, sex, color, national origin, marital status, disability, or veteran status with regard to employment, educational programs and activities, and/or admissions.

Issued in furtherance of Cooperative Extension work, acts of May 8 and June 30, 1914, in cooperation with the U.S. Department of Agriculture, Director of Oklahoma Cooperative Extension Service, Oklahoma State University, Stillwater, Oklahoma. This publication is printed and issued by Oklahoma State University as authorized by the Vice President for Agricultural Programs and has been prepared and distributed at a cost of 20 cents per copy. October 2026 CG.

FAPC-261-4