



## Food Dyes

Synthetic food dyes are often used in processed foods to add and enhance color and visual appeal. While concerns surrounding the use of these additives are not new, recent advocacy efforts have renewed public interest in calling for the removal of synthetic food dyes. Regulatory standards and labeling practices vary internationally and while some countries have banned or restricted certain dyes, others continue to allow their use. This inconsistency underscores the need to re-evaluate the role of synthetic food dyes in the modern food supply, especially in light of increasing demand for transparency and health-conscious choices.

The United States Food and Drug Administration (FDA) regulates food colors and requires evidence of safety before a color additive can be approved for use in food.<sup>1</sup> Safety is typically evaluated through animal toxicology studies, which identify the No Observed Adverse Effect Level (NOAEL), the highest tested dose at which no adverse effects are observed.<sup>2</sup> These adverse effects often include organ damage, cancer or reproductive harm. A 100-fold safety margin is incorporated to derive the Acceptable Daily Intake (ADI), or the estimated amount that can be consumed daily over a lifetime, without appreciable health risk.<sup>2,3</sup> If expected intake exceeds the ADI, additives may not be approved for use.

Permitted food colors are classified as either subject to certification or exempt from certification. To gain approval, color additives must undergo evaluation based on several criteria, including their chemical characteristics, typical consumption levels and both short- and long-term potential health effects.<sup>1</sup> The FDA also sets clear guidelines regarding which products an additive can be used in, the maximum allowable quantities and labeling requirements for consumer packaging.<sup>1</sup>

Colors exempt from certification include pigments from natural sources like vegetables, minerals or animals.<sup>1</sup> In contrast, certified color additives are synthetically produced and are required to undergo batch-by-batch certification for purity and identification.<sup>1</sup> Nine certified color additives have been approved for use in foods: Blue No. 1 and 2, Green No. 3, Red No. 3 and 40, Yellow No. 5 and 6, Orange B, and Citrus Red No. 2.<sup>4</sup> These dyes are mainly present in foods such as breakfast cereals, baked goods, candies, cake decorating icings, condiments, confections, drinks (including sports drinks, soft drinks and juices), gelatin and packaged goods.<sup>4</sup>

### Health Concerns

In 1975, Dr. Ben Feingold, a pediatric allergist, hypothesized that food additives, such as synthetic dyes, contributed to hyperactivity among children through allergenic or pharmacologic mechanisms.<sup>5</sup> Over the next several years, studies evaluated the impact of eliminating a variety of artificial colors, flavors and preservatives from the diet of children, a regimen that became known as the Feingold diet. A meta-analysis conducted in 1983 concluded that the effect of the Feingold diet on childhood hyperactivity was too small to be important.<sup>6</sup> Studies continued with randomized controlled trials investigating the effects of a food additive challenge, where participants were fed a dosage of a food additive and observed for behavioral changes. In 2004, Schab and Trinh<sup>7</sup> conducted a systematic review of these double-blind, placebo-controlled trials in subjects with baseline hyperactive syndromes. The meta-analysis indicated that food dyes promoted hyperactivity in hyperactive children, specifically for those children who were pre-screened for suspected sensitivity.<sup>7</sup> However, the effect was only significant for parent ratings of behavior, not clinician or teacher ratings. These early studies suffered from small sample sizes, inconsistent additive types and doses, inadequate blinding and subjective outcome measures.<sup>7</sup> A large clinical trial in 2007<sup>8</sup> evaluated the behavioral effects of two mixtures of artificial food colors and sodium benzoate. Results indicated that these mixtures were associated with increased hyperactivity in 3-year-old and 8-to-9-year-old children.

The methodological limitations within the bulk of available research contributed significant variability in findings. As a result, a 2011 hearing held by the FDA's food advisory committee voted not to ban artificial food colors or require a warning label,<sup>9</sup> however, concern persisted. A 2011 review concluded that a subgroup of children with attention deficit hyperactivity disorder (ADHD) are sensitive to artificial food additives and may benefit from a restricted diet.<sup>10</sup> Additionally, a 2022 study noted that animal toxicology studies used to establish ADI levels for the various synthetic dyes did not assess neurobehavioral risks.<sup>3</sup>

On January 15, 2025, the FDA announced revocation of authorization for the use of Red No. 3 in food and ingested drugs.<sup>11</sup> Red No. 3 had previously been shown to cause cancer in animal studies, placing its use in violation of the Delaney Clause.<sup>11</sup> This was followed by an April 22, 2025, announcement that the FDA would also revoke authorization for Citrus Red No. 2 and Orange B, as well as begin phasing out other synthetic dyes, including Green No. 3, Red No. 40, Yellow No. 5 and 6, Blue No. 1 and 2.<sup>12</sup> While some of these synthetic dyes have shown signs of DNA damage and oxidative stress in animal models<sup>13,14</sup> findings from high-dose animal studies are difficult to translate to humans with typical dietary exposure. These regulatory changes respond to long-standing health concerns regarding synthetic food dyes, particularly their potential effects on children's behavior.

## Overview of Evidence and Gaps Regarding Food Dye Effects

### Behavior

More recent systematic reviews have attempted to clarify the relationship between synthetic dyes and behavioral outcomes. Most human studies focus on children, as brightly colored foods are frequently marketed toward this population and children may be more vulnerable to potential harm due to higher intake relative to body weight and developing neurological systems.<sup>15</sup>

In 2012<sup>16</sup>, a meta-analysis was conducted to study the effect of a restricted diet, including synthetic dye elimination, on ADHD symptoms. Findings from this meta-analysis indicated that a restricted diet showed a small but significant reduction in ADHD symptoms in some children. However, restricted diets varied, with some studies vaguely describing this as a diet free of synthetic food colors and others eliminating not only artificial colors, but also flavors, preservatives, caffeine or any food that the individual child was thought to be sensitive to. Regarding the effect of food colors, challenge studies typically administered a specially prepared cookie, juice or capsule containing a food dye or mixture of dyes after the restricted diet period. The meta-analysis showed that the effects of food colors were linked to an increase in ADHD symptoms, especially based on parent reports (20 studies with 794 participants). However, this was not substantiated when analyzing results of a smaller number of teacher or observer reports (10 studies, 323 participants). Psychometric tests of attention conducted by observers in six studies suggested a significant effect of food dyes on attention. This 2012 meta-analysis concluded that an estimated 8% of children with ADHD may have symptoms related to synthetic food colors.

Building on this work, the California Office of Environmental Health Hazard Assessment (OEHHA) conducted a systematic review in 2021 on the impact of synthetic dyes on children.<sup>17</sup> A total of 27 studies were reviewed and included children with and without pre-existing behavioral disorders. Overall, the findings indicated that synthetic food dyes may trigger or make behavioral issues worse in certain children.<sup>17</sup> However, clear associations were not observed in every study. Out of 25 challenge studies, 13 showed a statistically significant association between synthetic dyes and behavioral issues. Most of these associations were found in studies using parent-reported outcomes. Eight of these studies included both parent and teacher reports, of which four studies found effects only when examining parent reports and one found associations for both parent and teacher reports.<sup>17</sup> OEHHA also concluded that sensitivity to food dyes likely varies greatly from person to person. However, there was not a clear source of bias that invalidated the observed associations. The report also found that existing ADI thresholds for food dyes would be considerably lower if neurobehavioral effects of more modern animal studies were used to establish these thresholds.

Despite these reviews, controversy has persisted. Most studies included in systematic reviews are several decades old and may not be reflective of how dyes are consumed today. Additionally, heterogeneity in dye and diet types, dosage and methods across studies has complicated a clear conclusion. Given the inconsistent effects and difficulty of isolating the effects of food dyes, a focus on broader dietary patterns may better reflect real-world exposure and cumulative effects on behavior. Food dyes are often a component of foods that are high in added sugars.<sup>18</sup> A 2019 meta-analysis of 14 observational studies found that diets high in refined sugar and saturated fat were a risk to ADHD, while higher intake of fruits and vegetables were protective against hyperactivity or ADHD.<sup>19</sup>

More research on diet, food additives and behavior is warranted. Additionally, nearly all studies on behavioral effects of synthetic dyes have been conducted in children; there is very little limited evidence examining behavior or cognitive effects in adults. Parents may choose to avoid or limit foods with synthetic dyes if their child's behavior is of concern. A diet that prioritizes whole foods has consistently shown health benefits while also decreasing exposure to food dyes.

### **Cancer**

To date, no human studies have shown a causal link between synthetic food dye exposure and cancer. Available data on carcinogenicity comes from animal and cell-line models. However, the role of poor dietary patterns in cancer risk is well-substantiated.<sup>20</sup> Artificial dyes are commonly associated with diets rich in processed snacks, sugary beverages, fast foods and low in whole grains, fruits and vegetables. This overall pattern, rather than the additives themselves, has been consistently linked with increased cancer risk.<sup>21</sup> Hence, the American Institute of Cancer Research recommends eating a diet rich in fruits and vegetables and avoiding or limiting processed foods high in fat and sugar to help lower the risk of cancer.<sup>22</sup>

### **Conclusion**

While some evidence suggests synthetic dyes may affect the behavior of a small subset of children, the findings are inconsistent. Similarly, concerns about cancer and food dyes are not based on human evidence. The conversation about synthetic food dyes highlights a deeper concern about the quality, accessibility and transparency of our modern food supply. Focusing on specific additives is a starting point in examining America's food supply but food dyes are one ingredient in a complex food environment. Abundant evidence suggests that improving overall diet quality through reducing the intake of foods high in added sugars and unhealthy fats while increasing access to whole, minimally processed foods offers more substantial and equitable benefits to human health. Advocacy efforts should prioritize policies that improve the affordability of and access to healthy, whole foods, rather than sole ingredient re-formulation of processed foods.

Note from the Academy of Nutrition and Dietetics:

This summary reflects findings from evidence-based research and is a high-level overview of food dyes; this summary is not a comprehensive deep-dive on the topic. The information shared in this summary is up to date as of June 2025.

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