

Synthetic Food Dyes and Behavioral Effects in Children

Evidence of the link between synthetic food dyes¹ and neurobehavioral problems in children—including hyperactivity and inattention—has been accumulating for decades.

Foods and drinks consumed by children often include synthetic dyes. One study found that about 90 percent of child-oriented candies, fruit-flavored snacks, and drink mixes/powders in a sampled grocery store contain synthetic dyes.² Such dyes are often used to make unhealthful foods visually appealing and may be a substitute for fruits and vegetables as ingredients in foods.

While there is no such requirement yet in the U.S., in the European Union, foods with specific dyes—including FD&C³ Red 40, Yellow 5, and Yellow 6, the three most commonly used dyes in foods in the U.S.⁴—must carry a warning label stating that the dyes “may have an adverse effect on activity and attention in children”.⁵ In Europe, many food manufacturers choose to use colorings derived from natural sources—such as fruit or vegetable extracts—and thus avoid the label.⁶

Recently, California’s Office of Environmental Health Hazard Assessment (OEHHA) conducted the most comprehensive and rigorous assessment undertaken to date of the relationship between synthetic dyes and effects on child behavior. It is the only assessment of synthetic food dyes that systematically examines evidence from humans (27 clinical trials in children), animals, and other studies that shed light on the mechanisms by which dyes can affect behavior.⁷ It also includes the most comprehensive and recent exposure data on synthetic food dyes to date. The assessment underwent peer review and public comment. The final assessment, issued in April 2021 concludes:

“The scientific literature indicates that synthetic food dyes can impact neurobehavior in some children. Data from multiple evidence streams, including epidemiology, animal neurotoxicology, *in vitro* and high throughput assays providing mechanistic insight, support this finding.”

OEHHA’s findings are fully in line with those of other independent reviews of the evidence, including three meta-analyses,^{8–10} a review on behalf of the European ADHD Guidelines Group,¹¹ a review using the Oxford Center for Evidence-Based Medicine guidelines,¹² and several other reviews.^{13–16}

The report also states that:

“At a minimum, in the short-term, the neurobehavioral effects of synthetic food dyes in children should be acknowledged and steps taken to reduce exposure to these dyes in children.”

Implications for Child Health

OEHHA’s report found that the levels (doses) of dyes considered “safe” by the Food and Drug Administration (FDA) do not adequately take neurobehavioral effects into account. As OEHHA states:

“The studies that form the basis of the US FDA... ADIs¹⁷ [safe or acceptable intake levels] ... are 35 to almost 70 years old, and as such were not capable of detecting the types of neurobehavioral outcomes assessed in later studies, or for which there is concern in children consuming synthetic dyes. The ADIs [acceptable intakes] for dyes where recent data exist (Red No. 3, Red No. 40, Yellow No. 5, Yellow No. 6) would be much lower if they were based on the results of more recent animal and human studies that focus on neurobehavioral effects. Common exposures to some synthetic food dyes from foods would exceed ADIs if they were based on more recent studies focused on neurobehavioral effects.”¹⁸

For example, the FDA’s “acceptable” level (ADI) for Yellow 5, one of the most common dyes used in food, is more than 60 times higher than the level that OEHHA and researchers identified as triggering neurobehavioral effects in a double-blinded, placebo controlled, study of young children.¹⁹⁻²¹ OEHHA’s assessment found that children under 16 years old consume, on average, at least as much Yellow 5 in a day than the amount that triggered adverse neurobehavioral effects in that study.^{22,23} OEHHA’s report did not establish “safe” levels of dyes, and instead advises that steps be taken to reduce children’s exposure to dyes.

According to the OEHHA report, examples of the neurobehavioral effects caused or exacerbated by dyes in some children include:

- hyperactivity,
- inattentiveness, and
- restlessness,

Some studies also report effects such as:

- sleeplessness,
- irritability, and
- aggression.²⁴

These effects may be short-term – occurring over hours, days, or even weeks—and resolve after discontinuation of exposure. Yet given the prevalence of synthetic food dyes in foods,

“For the child who is affected and their family, their teachers, and the school system, a short term increase in inattentiveness or restlessness and anxiety that can be repeated routinely when food dye is consumed could reduce social and academic success, and is thus adverse.” – OEHHA, 2021

supplements, and medications, it is likely that exposures and the related effects, will occur repeatedly in kids.

For these reasons, chronic exposures to dyes may impact children's ability to learn, succeed at school, and get along with peers on an on-going basis, with serious long-term consequences. The symptoms of synthetic food dye exposure overlap with ADHD (attention-deficit hyperactivity disorder) symptoms. ADHD is associated with lifelong impairment in functions and long-term outcomes that can include failure to complete high school, serious substance abuse, criminality, and depression.^{25,26} In fact, evidence indicates the elimination of food dyes is far more effective at treating ADHD than many other non-drug treatments for ADHD, although it is not as effective as FDA-approved drugs.²⁷

Disparities in Exposure

OEHHA found that total synthetic food dye exposures are higher among women of childbearing age with lower incomes ($\leq 130\%$ of federal poverty guidelines) compared to women of childbearing age with higher incomes ($> 130\%$ of federal poverty guidelines).²⁸ Additionally, non-Hispanic Black women of childbearing age and children of the same group have significantly higher intake compared to other ethnic groups.²⁹ These disparities in exposures occur in the context of pre-existing health disparities between income and racial groups that disadvantage historically marginalized people.

Policy Implications

To reduce the impact of synthetic dyes on children, state legislatures should:

- **Require warning labels on foods (including beverages) containing synthetic dyes (or at point of purchase, e.g., restaurant boards, as appropriate.)** A warning label similar to what is required in Europe will help inform consumers that synthetic dyes can impact behavior in children and can alert consumers to the presence of dyes in food.
- **Ultimately, ban synthetic dyes in foods and beverages, starting with foods served in schools and daycare centers.** OEHHA's health effects assessment and other independent scientific assessments conclude that synthetic food dyes can impact behavior in children. These dyes have no place in our children's foods and should be removed.

For more information, please contact the Center for Science in the Public Interest at policy@cspinet.org.

¹ This refers to the "numbered" dyes such as Yellow 5, sometimes listed as FD&C Yellow 5. "FD&C" is the abbreviation for the Federal Food, Drug, and Cosmetic Act, the law governing the use of color additives. Nine FD&C certified color additives are approved for use in food in the United States, including: FD&C Blue No. 1; FD&C Blue No. 2; FD&C Green No.3; FD&C Red No. 3; FD&C Red No. 40; FD&C Yellow No. 5; FD&C Yellow No. 6, Citrus Red No.2, and Orange B. Source: 21 CFR. § 74.101, 102, 203, 250, 302, 303, 340, 705, 706. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-74#_top.

² Batada A, Jacobson MF. Prevalence of artificial food colors in grocery store products marketed to children. *Clin Pediatr (Phils)*. 2016;55(12):1113-9.

- ³ Synthetic food dyes may be listed with or without “FD&C” before the name of the color. FD&C refers to “Food, Drug, & Cosmetic”, indicating that the color additive may be used in foods, drugs, and cosmetics. In contrast, “D&C” colorings may not be used in food, only drugs and cosmetics.
- ⁴ U.S. Food and Drug Administration. *Report on the Certification of Color Additives: 3rd Quarter, Fiscal Year 2021, April 1-June 30, 2021*. <https://www.fda.gov/industry/color-certification-reports/report-certification-color-additives-3rd-quarter-fiscal-year-2021-april-1-june-30>.
- ⁵ European Union, Regulation 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. *Off J Eur Union* L345:16–33 (2008).
- ⁶ Saltmarsh M. Recent trends in the use of food additives in the United Kingdom. *J Sci Food Agric*. 2015;95(4):649-652.
- ⁷ California Office of Environmental Health Hazard Assessment (OEHHA). *Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes in Children*. 2021. <https://oehha.ca.gov/media/downloads/risk-assessment/report/healtheffectsassess041621.pdf>.
- ⁸ Nigg JT et al. Meta-Analysis of attention-deficit/hyperactivity disorder or attention-deficit/hyperactivity disorder symptoms, restriction diet, and synthetic food color additives. *J Am Acad Child Adolesc Psychiatry*. 2012;51(1): 86-97.e8.
- ⁹ Sonuga-Barke EJ et al. Nonpharmacological interventions for ADHD: systematic review and meta-analyses of randomized controlled trials of dietary and psychological treatments. *Amer J Psychiatry*. 2013 Mar 1; 170(3):275-89.
- ¹⁰ Schab DW, Trinh N-H T. Do artificial food colorings promote hyperactivity in children with hyperactive syndromes? A meta-analysis of double-blind placebo-controlled trials. *J Dev Behav Pediatr*. 2004;25(6):423-34.
- ¹¹ Stevenson J et al. Research Review: The role of diet in the treatment of attention-deficit/hyperactivity disorder –an appraisal of the evidence on efficacy and recommendations on the design of future studies. *J Child Psychol Psychiatry*. 2014;55(5):416-27.
- ¹² Faraone SV, Antshel KM. Towards an evidence-based taxonomy of nonpharmacologic treatments for ADHD. *Child Adolescent Psychiatric Clin N Am*. 2014; 23(4):965–972.
- ¹³ Nigg, JT, Holton, K. Restriction and elimination diets in ADHD treatment. *Child Adolesc Psychiatr Clin N Am*. 2014 Oct;23(4):936-53.
- ¹⁴ Arnold LE et al. Attention-deficit/hyperactivity disorder: dietary and nutritional treatments. *Child Adolesc Psychiatr Clin N Am*. 2013; 22(3): 381–402.
- ¹⁵ Arnold LE et al. Artificial food colors and attention-deficit/hyperactivity symptoms: conclusions to dye for. *Neurotherapeutics*. 2012 Jul;9(3):599-609.
- ¹⁶ Stevens LJ et al. Dietary sensitivities and ADHD symptoms: thirty-five years of research. *Clin Pediatr (Phila)*. 2011;50(4):279-93.
- ¹⁷ ADI is an abbreviation for “Acceptable Daily Intake,” the amount of a substance that is considered safe to consume each day over the course of a person’s lifetime.
- ¹⁸ California OEHHA, 2021, p. 22.
- ¹⁹ California OEHHA, 2021, p. 274.
- ²⁰ Rowe KS, Rowe KJ. Synthetic food coloring and behavior: A dose response effect in a double-blind, placebo-controlled, repeated-measures study. *J Pediatr*. 1994;125(5 Pt 1):691-698.
- ²¹ Rowe and Rowe (1994) conducted a double-blinded, placebo-controlled trial testing the behavioral effects of multiple doses of Yellow No. 5 (0.1, 2, 5, 10, or 20 mg) in children (over half of whom did not have behavioral problems) and used a validated behavior test to measure the response. They found that behavior scores were significantly different in children on days they had received the dye versus when they received the placebo. Additionally, the higher the dose of dye, the worse the children scored. This kind of dose-response is strong evidence of a true effect. The mean behavior score difference between the group of children who reacted to dyes and the group that did not was statistically significant at doses of 2 mg and higher. Based on a reference body weight of 25.5 kg for a 7-year-old child, 2 mg of Yellow No. 5 is equivalent to a dose of 0.08 mg/kg-body weight/day. The ADI set by the FDA for Yellow No. 5 is 5 mg/kg-body weight/day, 62.5 times higher than the level identified by Rowe and Rowe that produced neurobehavioral effects in children. (Source: 50 Fed. Reg. 35776. FD&C Yellow No. 5 Final rule; removal of stay. <https://archives.federalregister.gov/issue/slice/1985/9/4/35772-35783.pdf#page=5>)
- ²² California OEHHA, 2021, p. 214.
- ²³ For example, for children between 5 and 9, OEHHA estimated that the mean intake under a typical exposure scenario was 0.11 mg/kg/day for a single day, slightly higher than the dose that caused behavioral effects in the Rowe and Rowe study (0.08 mg/kg/day). Of course, intakes under high-exposure scenarios, and under a typical exposure scenario using the 95th percentile instead of the mean intake resulted in even greater exceedances. For children under five intake was higher on a mg/kg/day basis than for children between ages 5 and 9. For children 9 to less than 16, the mean and 95th percentile intakes met or exceeded 0.08 mg/kg/day.
- ²⁴ California OEHHA, 2021, pp. 21, 116, 275.
- ²⁵ Erskine HE et al. Long-term outcomes of Attention-Deficit/Hyperactivity Disorder and Conduct Disorder: A systematic review and meta-analysis. *J Am Acad Child Adolesc Psychiatry*. 2016;55(10):841-50.
- ²⁶ Chronis-Tuscano A. Attention-Deficit/Hyperactivity Disorder (ADHD). Presentation to the FDA Food Advisory Committee, March 30, 2011. <https://wayback.archive-it.org/org-1137/20170406211701/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm271532.htm>.
- ²⁷ Faraone SV, 2014.
- ²⁸ California OEHHA, 2021, pp. 223-224.
- ²⁹ California OEHHA, 2021, pp. 224-225.