

# Synthetic Food Dyes and Behavioral Effects in Children: Implications for Regulators, Schools, and Daycare Centers

Evidence of the link between synthetic food dyes<sup>1</sup> and neurobehavioral problems in children, including hyperactivity and inattention, has been accumulating for decades.

Foods and drinks consumed by children—including those served in schools—include synthetic dyes. 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 Red 40, Yellow 5, and Yellow 6, which are the three most commonly used dyes in foods in the U.S.) must carry a warning label stating that the dyes: "may have an adverse effect on activity and attention in children."<sup>2</sup> As a result, in Europe, many food manufacturers choose to use colorings derived from natural sources, such as fruit or vegetable extracts, and thus avoid the label.<sup>3</sup>

For the past several years, California's Office of Environmental Health Hazard Assessment (OEHHA) has been conducting the most sophisticated and rigorous assessment undertaken to date of the relationship between synthetic dyes and effects on child behavior.

The OEHHA assessment is systematically examining evidence from 27 clinical trials in children, numerous animal studies, and other studies, that shed light on the mechanisms by which dyes can affect behavior.<sup>4</sup> The draft assessment, issued in September 2020 for public comment,<sup>5</sup> stated that:

"Based on multiple streams of evidence, the FD&C synthetic dyes cause or exacerbate neurobehavioral problems in children."

OEHHA's draft findings are consistent with those of other recent independent reviews of the evidence, including three meta-analyses,<sup>6,7,8</sup> a review on behalf of the European ADHD Guidelines Group,<sup>9</sup> a review using the Oxford Center for Evidence-Based Medicine guidelines,<sup>10</sup> and several other reviews.<sup>11,12,13,14</sup>

The draft report concludes 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 draft found that the levels (doses) of dyes considered "safe" by the Food and Drug Administration (FDA) do not adequately take neurobehavioral effects into account.<sup>15</sup> As OEHHA states, "[t]he animal studies that form the basis of the FDA's [acceptable exposure levels] are many decades old and were not capable of detecting the types of neurobehavioral outcomes measured in later studies, or for which there is concern in children consuming synthetic dyes."

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.<sup>16,17</sup>

Furthermore, OEHHA's draft assessment found that children under 16 years old consume, on average, more Yellow 5 than the amount that triggered adverse neurobehavioral effects in the study.<sup>18</sup> OEHHA's draft did not establish "safe" levels of dyes, and instead advises that steps be taken to reduce exposure to these dyes in children.

The neurobehavioral effects caused or exacerbated by dyes in children include:

- hyperactivity,
- inattentiveness, and
- restlessness,

Some studies also report effects such as:

- sleeplessness,
- irritability, and
- aggression.

These effects may be short-term (e.g., occurring

"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, 2020

over hours, days, or even weeks) and resolve after discontinuation of exposure. Yet given the prevalence of synthetic food dyes in foods, supplements, and medications, it is likely that exposures and, therefore, 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-type (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.<sup>19,20</sup> In fact, elimination of food dyes is considered to be an effective non-drug treatment for some children with ADHD.<sup>21</sup>

#### 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 with higher incomes (> 130% of federal poverty guidelines). Additionally, non-Hispanic Black women of childbearing age and children of the same group have significantly higher intake compared to other racial groups. These disparities in exposures occur in the context of pre-existing health disparities between income and racial groups that disadvantage historically marginalized people.

### Synthetic Dyes in Schools

Synthetic food dyes are commonplace on supermarket shelves and in school foods.

Cheetos® Fantastix!® Flamin' Hot® Corn and Potato Snacks (pictured right) is promoted as meeting USDA's whole grainrich criteria, but also contains Red 40 Lake, Yellow 6 Lake, and Yellow 6.<sup>22</sup>







Dole Cherry Mixed Fruit Cup (pictured left) is touted for containing 100% juice and depicts fresh fruit on the front of package. What's not clear from the front label? That it contains Red No. 3.<sup>23</sup> Unsuspecting consumers might identify this as a natural, healthy choice and not be aware that it contains synthetic dyes.

To reduce the impact of synthetic dyes on children, state and local government, schools/school districts, and daycare centers should:

- Require warning labels on (or at point of purchase, as appropriate) foods (including beverages) containing synthetic dyes. A warning label, similar to what is required in Europe, will help inform consumers that synthetic dyes may cause or exacerbate adverse behavior in children and can alert consumers to the presence of dyes in food.
- Prohibit synthetic dyes in foods (including 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 cause or exacerbate neurobehavioral effects 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 <u>policy@cspinet.org</u>.

<sup>14</sup> Stevens LJ et al. Dietary sensitivities and ADHD symptoms: thirty-five years of research. Clin Pediatr (Phila). 2011;50(4):279-93.

<sup>16</sup> 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.

<sup>17</sup> 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.

<sup>18</sup> 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 and the 2-day average was 0.09 mg/kg/day, slightly higher than the dose that caused behavioral effects in the Rowe and Rowe study (0.08 mg/kg/day). <sup>19</sup> 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. <sup>20</sup> Chronis-Tuscano A. Attention-Deficit/Hyperactivity Disorder (ADHD). Presentation to the FDA Food Advisory Committee, March 30, 2011.

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it.org/org1137/20170406211701/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm271532.htm. <sup>21</sup> 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

Cheetos. CHEETOS® FANTASTIX® FLAMIN' HOT® Flavored Baked Corn & Potato Snacks. n.d. https://www.cheetos.com/products/cheetos-fantastix-<u>famin-hot-flavored-baked-com-potato-snacks</u>. Accessed January 5, 2021.
<sup>23</sup> Dole. 36/4 Cherry Mixed Fruit Juice. n.d. <u>http://www.dolefoodservice.com/product/47</u>. Accessed January 5, 2021.

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<sup>&</sup>lt;sup>1</sup> This refers to the "numbered" dyes such as Yellow 5 and Red 40. Synthetic food dyes are substances widely used in food due to their intensity and uniformity of color. Nine Food, Drug, and Cosmetic Act (FD&C) batch certified color additives are approved 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. <sup>2</sup> 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).

<sup>&</sup>lt;sup>3</sup> Saltmarsh M. Recent trends in the use of food additives in the United Kingdom. J Sci Food Agric. 2015;95(4):649-652.

<sup>&</sup>lt;sup>4</sup> California Office of Environmental Health Hazard Assessment. Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes in Children [Draft]. 2020. https://oehha.ca.gov/media/downloads/risk-assessment/report/fooddyesassessmentdraft082820.pdf. Accessed November 9, 2020.

<sup>&</sup>lt;sup>5</sup> The assessment was published as a draft in August 2020 and circulated for peer review and public comment and has not yet been finalized

<sup>&</sup>lt;sup>6</sup> 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.

Sonuga-Barke EJ et al. Nonpharmacological interventions for ADHD: systematic review and metaanalyses of randomized controlled trials of dietary and psychological treatments. Amer J Psychiatry. 2013 Mar 1; 170(3):275-89. <sup>8</sup> 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. <sup>9</sup> 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.

<sup>&</sup>lt;sup>10</sup> 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.

<sup>&</sup>lt;sup>11</sup> Nigg, JT, Holton, K. Restriction and elimination diets in ADHD treatment. Child Adolesc Psychiatr Clin N Am. 2014 Oct;23(4):936-53.

<sup>&</sup>lt;sup>12</sup> Arnold LE et al. Attention-deficit/hyperactivity disorder: dietary and nutritional treatments. Child Adolesc Psychiatr Clin N Am. 2013; 22(3): 381–402.

<sup>&</sup>lt;sup>13</sup> Arnold LE et al. Artificial food colors and attention-deficit/hyperactivity symptoms: conclusions to dye for. *Neurotherapeutics*. 2012 Jul;9(3):599-609.

<sup>&</sup>lt;sup>15</sup> This finding was observed for Red No. 3, Blue No. 1, Red No. 40, and Yellow No. 5.