May 12, 2023

Benson Yee, Chief
Food and Drug Branch
California Department of Public Health (CDPH)
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Re: Support for P-22-01 – Synthetic Dye Warning Label Petition

Dear Mr. Yee:

The undersigned strongly support Petition P-22-01 submitted by the Center for Science in the Public Interest, Breast Cancer Prevention Partners, Center for Food Safety, Children's Advocacy Institute, Consumer Federation of America, Environmental Working Group, Life Time Foundation, Public Health Institute, Linda Birnbaum, and Lisa Lefferts, which would require warning labels on foods, beverages, and supplements in California that contain synthetic food dyes.

The petition urges CDPH to act on the comprehensive and rigorous assessment by your sister agency, the California Office of Environmental Health Hazard Assessment (OEHHA),[1] and require warning labels on dyed foods and supplements, similar to what Europe has required for over a decade for most dyed foods.

The OEHHA assessment used a state-of-the-art structured approach of systematic review and evidence integration to evaluate potential neurobehavioral effects of synthetic food dyes. It has been applauded by physicians, researchers, and health-based organizations. The assessment was peer-reviewed and all peer-reviewers supported the conclusions, calling it "an impressive review," "comprehensive," and "well-supported."[2] Its findings are fully in line with those of other independent reviews of the evidence, including three meta-analyses,[3-5] a review on behalf of the European ADHD Guidelines Group,[6] a review using the Oxford Center for Evidence-Based Medicine guidelines,[7] and several other reviews.[8-11]

OEHHA concluded:

> "The scientific literature provides evidence in humans and animals, as well as mechanistic information, that synthetic food dyes can cause or exacerbate neurobehavioral problems in some children. Data from multiple evidence streams, including epidemiology, animal neurotoxicology, in vitro and high throughput assays providing mechanistic insight, taken together, provide support that FD&C batch-certified synthetic food dyes can impact neurobehavior in some children."[12]

And:

> "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."[13]

A warning label on products containing synthetic food dyes would do just that.

Synthetic food dyes are widely used. According to FDA estimates, 100% of people over age 2 are exposed to synthetic food dyes. OEHHA found that total synthetic food dye exposures are higher among women of childbearing age with lower incomes compared to those with higher incomes; and that overall,

non-Hispanic Black participants had significantly higher intake compared to other groups (Hispanic, non-Hispanic White, and Asian or other categories).[14]

Dyes are unnecessary and provide no nutritional or health benefit; in fact, they sometimes displace healthy, colorful fruits and vegetables. It is not always obvious that foods contain synthetic food dyes.[15] Consumers may not even realize that many foods contain dyes or think to check the ingredients list for dyes. Moreover, many parents are unaware of the link between dyes and adverse behavior, and so are unable to identify dyes as a cause of their children's behavioral problems.

Parents, caretakers, schools, and others that provide food or supplements for children should be informed before buying food and supplements with synthetic food dyes so they can protect children's health and wellbeing. They have the right to guide children's food choices based on clear and conspicuous information about potential adverse reactions that ingredients may cause. CDPH could ensure that food and supplement labels provide that information for synthetic food dyes. We urge CDPH to approve petition P-22-01 without delay.

Signatories:

Organizations

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cc: Dr. Tomás J. Aragón, Director

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[1] 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/healthefftsassess041621.pdf.

[2] Peer-reviewer 1 (Emanuela Taioli MD, PhD) stated "outstanding job in summarizing and interpreting the available epidemiologic data" and concluded "This is an impressive review." Peer-reviewer 2 (Peter Spencer, PhD, FANA, FRCPath) called the assessment "a comprehensive study" and stated "The reviewer supports the general conclusion, "The scientific literature provides evidence in humans and animals, as well as mechanistic information, that synthetic food dyes may cause or exacerbate neurobehavioral problems in some children." Peer-reviewer 3 (Emily Barrett, PhD) stated "The report is quite comprehensive in its data extraction and summaries," "Conclusion 1 remains well-supported," and "In summary, this reviewer affirms the quality of the systematic review of the epidemiologic literature, the results of which support Conclusion 1."

[3] 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.

[4] 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.

[5] 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.

[6] 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.

[7] 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.

[8] Nigg, JT, Holton, K. Restriction and elimination diets in ADHD treatment. Child Adolesc Psychiatr Clin N Am. 2014 Oct;23(4):936-53.

[9] Arnold LE et al. Attention-deficit/hyperactivity disorder: dietary and nutritional treatments. Child Adolesc Psychiatr Clin N Am. 2013; 22(3): 381–402.

[10] Arnold LE et al. Artificial food colors and attention-deficit/hyperactivity symptoms: conclusions to dye for. Neurotherapeutics. 2012 Jul;9(3):599-609.

[11] Stevens LJ et al. Dietary sensitivities and ADHD symptoms: thirty-five years of research. Clin Pediatr (Phila). 2011;50(4):279-93.

[12] OEHHA 2021, page 279.

[13] OEHHA 2021, page 286.

[14] OEHHA 2021, pages 223-225.

[15] For example, some brands of chocolate cakes (e.g., Little Debbie Swiss Rolls) contain synthetic dyes and others (e.g., Hostess Ho Hos) do not. Surprisingly, even some pickles, salad dressing, marshmallows, vanilla frosting, and Pediasure chocolate shakes contain dyes.