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September 25, 2020

Environmental Working Group (EWG) comments on the California Office of Environmental Health Hazard Assessment draft “Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes in Children”

Submitted via electronic docket at <https://oehha.ca.gov/comments>

The Environmental Working Group, a nonprofit research and policy organization with offices in San Francisco, Sacramento, Minneapolis and Washington, D.C., submits these comments to the California Office of Environmental Health Hazard Assessment on the draft assessment “Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes in Children.” EWG supports OEHHA’s timely review of synthetic food dyes and agrees with OEHHA’s conclusion that they “may cause or exacerbate neurobehavioral problems in some children.”

EWG has studied food dyes extensively and included them in our consumer guide¹ for food additives. Our organization has long advised parents and families to limit children’s consumption of these food additives, because of their potential to cause behavioral effects and other health harms. The current legally allowable Acceptable Daily Intake, or ADI, for food colorants was set by the Food and Drug Administration decades ago, based on toxicological studies that are now 35 to 70 years old. These earlier studies in laboratory animals were not capable of detecting the types of neurobehavioral identified by contemporary epidemiological research.² Thus, we wholeheartedly agree with OEHHA’s conclusion that the legally allowable ADIs do not protect children’s health. We support OEHHA’s recommendation to limit children’s exposure to food dyes, and we find it disconcerting that food dyes that may harm health continue to be added to foods, especially those popular with children.

In its health assessment of seven synthetic food dyes, OEHHA found that these dyes are associated with adverse neurobehavioral outcomes in children and that children vary in their sensitivity to exposure. These findings were supported by data from epidemiological studies, neurotoxicity studies in animals, and high-throughput and *in vitro* assays. Studies in humans showed that dyes were associated with the neurobehavioral effects of inattentiveness, hyperactivity and restlessness in sensitive children. In studies in adult animals, exposure to Red No. 3, Red No. 40, Yellow No. 5 and Yellow No. 6 resulted in altered brain chemistry. Exposure to Red No. 40 and Yellow No. 5 was associated with altered learning and memory and changes in brain cells, and exposure to Red No. 3 and Yellow No. 5. resulted in changes in activity and brain chemistry.

¹ Environmental Working Group. “Food Additives State of the Science.” Available at: <https://www.ewg.org/research/food-additive-science/>

² Trasande L, Shaffer RM, Sathyanarayana S; Council On Environmental Health. 2018. Food Additives and Child Health. *Pediatrics* 142(2):e20181410. <https://doi.org/10.1542/peds.2018-1410>



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From OEHHA's exposure assessment, the highest exposure was from Red. No. 40, followed by Yellow No. 5 and Yellow No. 6. It was found that dyes in children's over-the-counter medicine and vitamins were a source of higher exposure compared to food, especially for Red No. 40. Several doses of medicine in a day could lead to exceeding the current legally allowable daily intake. The most common food sources were juice drinks, fruit-flavored beverages, soft drinks, ice cream cones, breakfast cereal and icing. In addition to these types of products, synthetic food colorants are present in numerous foods on the market, which makes them hard to avoid.

OEHHA has recommended additional regulatory studies to determine safer, updated ADIs for food dyes. Although more research is always valuable, EWG finds that the existing body of research is sufficient to permit the steps necessary to protect the most sensitive children. Rowe and Rowe observed behavioral effects of irritability, restlessness and sleeplessness in children who were exposed to Yellow No. 5 at levels of just 1 mg.³ Therefore, it is important to address the immediate need to alert parents to these harms in food products marketed to children and reduce their exposure. Since 2010, food sold in the European Union with any one of six dyes, including Yellow No. 5, Yellow No. 6 and Red. No. 40, must be labeled with the warning "may have an adverse effect on activity and attention in children."⁴

Finally, EWG agrees with OEHHA's methodology of using multiple data streams, including high throughput toxicology data, to assess the neurotoxicity of food dyes in children, and we support OEHHA's recommendation of reducing children's exposure to these substances.

Submitted on behalf of the Environmental Working Group,

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³ Rowe KS, Rowe KJ. 1994. Synthetic food coloring and behavior: a dose response effect in a double-blind, placebo-controlled, repeated-measures study. *The Journal of Pediatrics*. 125(5): 691-8.
[https://doi.org/10.1016/s0022-3476\(94\)70059-1](https://doi.org/10.1016/s0022-3476(94)70059-1)

⁴ Lehto S, Buchweitz M, Klimm A, Straßburger R, Bechtold C, Ulberth F. 2017. Comparison of food colour regulations in the EU and the US: a review of current provisions." *Food Additives & Contaminants: Part A*: 34(3): 335-355. <https://doi.org/10.1080/19440049.2016.1274431>