November 6, 2020

Dr. Mark Miller
Air, Community, and Environmental Research Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

VIA ELECTRONIC MAIL ONLY

RE: Comments in Response to the Public Review Draft of *Health Effects Assessment: Potential Neurological Effects of Synthetic Food Dyes in Children*

Dr. Miller,

As requested by the California legislature, the Office of Environmental Health Hazard Assessment (OEHHA) was to perform a risk assessment limited to nine currently approved certified colors: FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, Orange B, Citrus Red No. 2, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5 and FD&C Yellow No. 6 and their potential neurological effect on children. On behalf of the undersigned associations and entities (hereafter "coalition"), thank you for the opportunity to provide comments to OEHHA on the above-referenced public review draft titled *Health Effects Assessment: Potential Neurological Effects of Synthetic Food Dyes in Children*. The coalition additionally incorporates by reference the comment letter from the International Association of Color Manufacturers (IACM). The coalition and IACM have been working collaboratively to review and respond to OEHHA's public review draft.

As a prefatory matter, we remind OEHHA that the U.S. Food and Drug Administration (FDA) has an extensive premarket approval and market surveillance program for the use of synthetic food colors. Any additional regulatory action by OEHHA or the California Legislature will create confusion in an area where the FDA has sole and preeminent responsibility. The potential patchwork of laws at the state level will generate confusion among consumers. Clear, simple, and consistent national regulation informed by risk-based science will enhance consumer trust in these products. FDA currently provides this leadership.

In addition, robust reviews of the health impacts of synthetic food colors conducted by scientific bodies including the FDA and the European Food Safety Authority (EFSA) have generally found these ingredients to be safe for use as food additives. As such, the claims suggesting synthetic food colors cause possible attention deficit disorder / hyperactivity in children is not scientifically substantiated. Existing risk assessments by international bodies have dismissed and discounted much of the available neurobehavioral evidence in this respect. Rather, the basis and nature of the OEHHA risk assessment was precipitated by legislative interest and policy driven conclusions predicated on casual correlation. With this in mind, we would like to emphasize the following points:

Synthetic Food Colors are Recognized as Safe

In March 2011, the FDA Food Advisory Committee (FAC), an expert panel of pediatricians, toxicologists, behavioral scientists, food scientists, and scientists in related fields, convened for a meeting to review all the available scientific data investigating a correlation between color additive intake and hyperactive behavior in children. After two days of scientific discussion, presentations by researchers, and public comment by parents and stakeholders, the FAC recommended that no warning label on products was needed to ensure the safe use of colors as food additives. The FAC concluded, based on all available evidence, that a causal relationship between the intake of synthetic color additives and hyperactivity in children could not be established.

Specific to the colors OEHHA is reviewing, seven of the nine certified color additives (all but Orange B and Citrus 2 of which have little to no documented U.S. or international use) have been recently evaluated for their safety by international regulatory bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and by the EFSA, both of which have concluded that they continue to be safe for all ages, including children. Both JECFA and EFSA have evaluated and concluded that the available literature does not provide compelling evidence to raise any concern about impacts to ADHD or any neurobehavioral effects from consumption of synthetic colors.

Synthetic Colors Have an Important Role

Color additives play an important role in food and they do so without posing a health risk to consumers. The most important benefit is the organoleptic property that indicates the palatability, or tastiness, of a product. Research has consistently shown that if foods don't have the right color, people won't eat them. Colors are added to ensure an even, consistent appearance that meet consumer expectations and preferences. During processing, the naturally occurring color in foods is often lost, which can make otherwise nutritious foods unappealing to humans.

Consumers Can Easily Identify Synthetic Colors by Name on Food Labels

In the U.S., each of the nine certified colors of interest to OEHHA is required to be listed by name on the product label in such a way as to allow consumers to make informed choices. In addition, manufacturers are providing information to consumers in the formats they want, including digitally. The COVID pandemic has expedited the sharing of product information digitally and consumers are using digital disclosure platforms to seek product information as they make decisions.

The Risk Assessment's Underlying Assumptions are Misapplied

Without establishing a neurobehavioral hazard for food colors, it is not possible to conduct a risk assessment for food colors, particularly one based on suggested neurobehavioral impacts in human trials burdened by significant limitations and

confounders. OEHHA's draft report often emphasizes results from select *in vitro* studies that help support a presumed conclusion (i.e., that color additives affect behavior). At the same time, OEHHA diminishes other *in vitro* and *in vivo* data (e.g., Lok et al., 2013) that reach a different conclusion indicating a lack of evidence for neurobehavioral impacts.

The coalition (as provided with additional detail in IACM's comment letter) also has concerns with the follow items:

- In drawing its conclusions, OEHHA gives significant weight to non-guidance studies where weak statistical analysis is used to accentuate inconsistent signals. OEHHA also draws conclusions from "noise" in animal or in vitro studies and prioritizes such findings despite overwhelming evidence that supports a conclusion of no effect. Conversely, a lack of consistent results among studies generally leads to a weight-of evidence conclusion that an identifiable hazard does not exist.

- The majority of meta-analyses and systematic reviews of those meta-analyses published in the last 5-7 years have concluded that dietary intervention methods, including diet restriction approaches (including color restricting) and those that are pro-nutrient, do not significantly alter children's behavior. These conclusions do not support an association between food colors and neurobehavioral endpoints and should be appropriately considered within OEHHA's analysis and report.

- The OEHHA report has a significant flaw regarding its inclusion of studies. While the report suggests that it has taken a systematic approach in its literature search and review, it does not describe the criteria used to qualify or exclude studies. This leaves the impression that OEHHA's weighting of studies in drawing conclusions is either arbitrary, selective for those that fit a narrative, or both.

- Studies of mixtures of food colors are not appropriate for hazard identification. They do not allow the identification of specific food colors that might pose a hazard, if such a hazard exists. Additionally, many of the studies include color additives within the mixtures that are not approved for use in the United States nor within the scope of OEHHA's review. In fact, by considering combinations of colors, OEHHA has, in many cases, asserted effects for color additives that likely have no contribution to the identified hazard, if such a hazard exists at all within the study

- Clear evidence of causality must be present for risk management actions to be warranted and OEHHA does not provide any conclusive evidence.

In conclusion, it has been our repeated position that to single out synthetic colors as a focus of investigation is not a productive strategy for addressing an important disorder such as ADHD. The legislative interest and inquiry does not in and of itself establish significant questions of fact or dispute to suggest a hazard exists. The evidence, when appropriately contextualized, does not support discriminating against food colors within our national food safety program. We support federal regulations that result in uniform structures, empower consumers to make informed decisions, and are grounded in risk-based science. When a patchwork of regulatory policies exists, it contributes to consumer confusion and adds unnecessary stress to the supply chain resulting in higher prices.

If you have any questions, please contact John Hewitt at (916) 508-6278 or jhewitt@consumerbrandsassocaiton.org

Sincerely,

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