

February 19, 2019

Office of Environmental Health Hazard Assessment
1515 Clay Street, 16th Floor
Oakland, CA 94612
Attention: Anna Smith, Food Dye Study

VIA ELECTRONIC MAIL ONLY

RE: Comments in Response to “Request for Information on the Neurologic and Neurobehavioral Impacts of Synthetic Food Dyes”

Dear Ms. Smith:

Thank you for the opportunity to provide comments to the Office of Environmental Health Hazard Assessment (OEHHA) on the above-referenced “Request for Information” on the nine currently approved certified colors in its assessment: 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. The undersigned entities hereby incorporate by reference the comment letter submitted by the International Association of Color Manufacturers.

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. 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 found these ingredients to be safe for use as food additives. The claims linking synthetic food colors with possible attention deficit disorder / hyperactivity are not scientifically sound enough to support a meaningful risk assessment. We would like to emphasize the following points:

Synthetic Food Colors are 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 additional information, including a 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 cause concern about impacts to ADHD 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 to indicate 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. During processing, the naturally occurring color in foods is often lost, which can make otherwise nutritious foods unappealing to humans.

Synthetic Colors Do Not Cause ADHD

The hypothesis that synthetic colors cause behavioral effects in children is not supported by regulatory agencies, scientific publications, nor the association representing people with attention deficit disorders The Attention Deficit Disorder Association **explicitly states** that Attention Deficit Hyperactivity Disorder (ADHD) is caused by chemical, structural, and connectivity differences in the brain, and that it is not caused by "poor parenting, falls or head injuries, traumatic life events, digital distractions, video games and television, lack of physical activity, food additives, food allergies, or excess sugar." OEHHA and the California Legislature should consider the diagnosis of ADHD as the serious public health issue that it is and should encourage viewing the risk management of ADHD holistically. ADD and ADHD are complex, multi-factorial conditions that require more serious medical and regulatory attention. To single out nine certified synthetic color additives as a focus of investigation is neither a systematic nor a productive strategy for addressing the issue. With flawed scientific justification, this approach instead diverts attention and resources from responsible investigation and interventions. To the extent animal studies are submitted to OEHHA for consideration they should not be given credence. Neurobehavioral effects in animal studies have been reviewed by expert organizations like JECFA and EFSA, who concluded that these studies do not provide evidence that warrants the revision to acceptable daily intakes. Rodent models of ADHD have been recently developed, but animal models can only evaluate proxy endpoints or certain aspects of the complex symptomatology ascribed as ADHD and at best provide feasible hypotheses regarding the underlying causes of specific aspects of ADHD behavior.

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. To the extent a consumer would like to know or avoid certain colors, they can.

In conclusion, to single out synthetic colors as a focus of investigation is neither a systematic nor productive strategy for addressing an important issue. California should support holistic approaches to addressing ADHD. The evidence does not support treating food colors as a risk factor for ADHD. If you have any questions, please contact John Hewitt at (916) 508-6278 or jhewitt@gmaonline.org.

Sincerely,

Fredericka McGee
American Beverage Association

Tim Shestek
American Chemistry Council

Valerie Nera
California Chamber of Commerce

Dawn Koepke, on behalf of the
California Manufacturers and Technology Association

Pamela Williams
California Retailers Association

John Hewitt
Grocery Manufacturers Association

Sarah Codrea
International Association of Color Manufacturers

Robert Rankin
International Food Additives Council

Liz Clark
National Confectioners Association

Trudi Hughes
California League of Food Producers

Jay Sirois
Consumer Healthcare Products Association