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## RESPONSE TO PETITION

### ABSTRACT:

The California Department of Public Health (CDPH) responds to a petition from the Center for Science in the Public Interest (CSPI), et al., requesting a warning label for packaged, unpackaged, bulk foods/supplements, and restaurant foods (menu icons) containing synthetic dyes. After careful consideration, CDPH denies the petition.

### BACKGROUND:

The Food and Drug Branch (FDB), as part of CDPH, regulates manufactured food, dietary supplements, and synthetic food additives under the Sherman Food, Drug, and Cosmetic Act (Sherman); Division 104, Part 5 of the California Health and Safety Code (H&SC) commencing with § 109875, and adopted federal law. Specifically, the state adopts federal regulations for color additives pursuant to H&SC § 110090. FDB ensures food products are not misbranded, adulterated, or falsely advertised.

CDPH does not directly regulate retail food facilities but acts as a technical advisor to local health departments who inspect retail food facilities to enforce the California Retail Food Code (CalCode), which is outside of Sherman's authority. Local enforcement agencies in California have the primary responsibility of retail enforcement. The purpose of the CalCode is to provide uniform statewide health and sanitation standards for retail food facilities, safeguard public health, impart sanitation standards, and provide consumers food that is safe, unadulterated, and honestly presented through the adoption of science-based standards.

The petition (received by CDPH December 8, 2022) relates to seven Federal Food, Drug, and Cosmetic Act (FD&C) color additives approved for use in food by the U.S. Food and Drug Administration (FDA) (FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40, and FD&C Yellow Nos. 5 and 6). In California, FD&C Red No. 3 has since been prohibited in the manufacturing, selling, delivering, distributing, holding, or offering for sale of a human food product beginning January 1, 2027, pursuant to AB 418 (Gabriel, 2023). Therefore, CDPH focused its analysis on the remaining six FD&C color additives and did not address FD&C Red No. 3.

### SUMMARY OF REQUESTED CHANGES:



The Petitioners are requesting that CDPH promulgate regulations that will require the following warning labels on food, dietary supplements, and restaurant foods that contain synthetic food dye (FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40, and FD&C Yellow Nos. 5 and 6), subject to batch certification by the FDA:

Warning for packaged, unpackaged, & bulk foods/supplements containing synthetic dyes:

*WARNING: Product contains synthetic food dyes which the State of California has determined can result in hyperactivity and other neurobehavioral problems in some children*

Warning for restaurant foods containing synthetic dyes:

*WARNING: Items indicated with [insert food dye warning icon] contain synthetic food dyes which the State of California has determined can result in hyperactivity and other neurobehavioral problems in some children*

**DISCUSSION:**

CDPH acknowledges the significance of safeguarding children from the detrimental effects of chemicals in food, and the intricacy involved in assessing the safety of chemicals before they are added to food. CDPH carefully considered the request, and examined available data to understand the problem this petition is trying to address and the approach proposed. In conclusion, CDPH cannot support the changes specified in the petition for the following reasons:

1. The petition provided to CDPH included literature on the topic of synthetic food dye consumption and its potential impact on the development of neurobehavioral effects in children. CDPH reviewed the studies provided with the petition and conducted our own search of scientific manuscripts. There is a significant body of literature that discusses the uncertainty in the evidence about the adverse effects of synthetic food dye consumption, and there is no scientific consensus on what the adverse effects are, what sensitive subpopulations are affected, and what levels of concern might be.
2. Food label warning statements are a useful tool to inform consumers when significant scientific agreement indicates a link between a particular food (or component of a food) and a disease or adverse health condition. When the link is not strong or universal, food label warning statements may not be effective, may be counterproductive, and/or may cause undue anxiety and alarm. In the case of synthetic food dyes, a review of scientific research indicates there was no definitive conclusion that synthetic food dyes trigger behavioral responses in children. There is some evidence that synthetic food dyes may trigger behavioral responses in *some* children and therefore a response that depends on the individual child and more research is needed to determine the factors that predispose certain children towards sensitivity to a defined dose of a specific artificial food dye. There could be a different triggering food (or food component) for each affected child.

In closing, current federal regulation, adopted by California, already requires ingredients (including certified colors) to be identified by name on product labels to help consumers choose products.

For the reasons listed above, CDPH must deny the petition.

#### CDPH CONTACT PERSON

Please direct any inquiries regarding this action to:

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#### AVAILABILITY OF PETITION

Any interested persons may obtain a copy of the petition that is the subject of this decision by sending a request to CDPH contact person listed in this notice or by emailing [Regulations@cdph.ca.gov](mailto:Regulations@cdph.ca.gov). When submitting such a request, please reference CDPH PETITION RESPONSE P-22-001 in the request.