

**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 S. BIRNBAUM, AND LISA Y. LEFFERTS**

12/8/22

Benson Yee, Chief  
Food and Drug Branch  
California Department of Public Health  
P.O. Box 997435, MS 7602  
Sacramento, CA 95899

**Re: PETITION FOR RULEMAKING TO IMPLEMENT WARNING LABELS ON FOOD PRODUCTS AND DIETARY SUPPLEMENTS THAT INCLUDE CERTAIN SYNTHETIC FOOD DYES**

Dear Mr. Yee:

Pursuant to California Government Code sections 11340.6 and 11340.7 and California Health and Safety Code sections 110070, 110075, and 110090, the Center for Science in the Public Interest, Children's Advocacy Institute, Environmental Working Group, Public Health Institute, Consumer Federation of America, Center for Food Safety, Life Time Foundation, Breast Cancer Prevention Partners, Lisa Y. Lefferts, and Linda S. Birnbaum on behalf of the children and families of California respectfully petition the California Department of Public Health (CDPH or the "Department") to promulgate regulations requiring the following warning labels on food and dietary supplement products that contain synthetic food dyes subject to batch certification by the U.S. Food and Drug Administration (FDA):<sup>1</sup>

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*

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<sup>1</sup> U.S. Food and Drug Administration. Summary of Color additives for use in the United States in Foods, Drugs, Cosmetics, and Medical Devices. Updated: 4 March 2022. Accessed: 23 Nov 2022. <https://www.fda.gov/industry/color-additive-inventories/summary-color-additives-use-united-states-foods-drugs-cosmetics-and-medical-devices>.

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*

Without such warnings, foods and supplements containing these dyes should be considered misbranded under sections 110290 and 110660 of the California Health and Safety Code as these products' labels or menus fail to reveal significant health risks posed by synthetic dyes which have been firmly established by the state of California.<sup>2</sup>

These synthetic food dyes were the subject of a health effects assessment by the California Office of Environmental Health Hazard Assessment (OEHHA). After comprehensively and systematically reviewing the evidence, OEHHA concluded in a 2021 peer-reviewed report that these dyes “cause or exacerbate neurobehavioral problems in some children.”<sup>3</sup> The OEHHA report specifically implicated the color additives FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6.<sup>4</sup>

As provided for in sections 11340.6 of the California Government Code and 110075 of the California Health and Safety Code, petitioners provide below (I) the reason for the request, (II) the authority of the state agency to take the action requested, and (III) the substantive nature of the regulation requested (including a draft of its proposed warning labels).

**I. REASONS WHY WARNING LABELS ARE NEEDED FOR FOOD AND DIETARY SUPPLEMENT PRODUCTS THAT INCLUDE CERTAIN SYNTHETIC DYES.**

The State of California has determined that certain synthetic food dyes harm some consumers, and per OEHHA, “[a]t 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.”<sup>5</sup> Requiring warning labels for food and dietary supplement products that contain synthetic food dyes would accomplish both of these goals.

Warning labels would inform consumers—especially parents, guardians, schools, and others who purchase food and supplement products for children—about the harmful effects of synthetic food dyes and allow them to make informed decisions about whether or not to purchase the product or serve it to children. In effect, warning labels should lead to reductions in children’s exposures to synthetic food dyes, thus producing the outcome recommended by OEHHA.

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<sup>2</sup> California Health & Safety Code 110290 (“In determining whether the labeling or advertisement of a food...is misleading,...[t]he extent that the labeling or advertising fails to reveal facts concerning the food... consequences of customary use of the food... shall also be considered.”).

<sup>3</sup> 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/healtheffectsassess041621.pdf>.

<sup>4</sup> Orange B and Citrus Red No. 2 are also color additives subject for batch certification and approved for use in foods and supplements but are not used according to FDA color certification reports (<https://www.fda.gov/industry/color-certification/color-certification-reports>) and the OEHHA report.

<sup>5</sup> California OEHHA 2021. P. 286.

OEHHA conducted the most comprehensive and rigorous assessment undertaken to date of the relationship between synthetic dyes and effects on child neurobehavior. It is the only assessment of synthetic food dyes that systematically examined evidence from humans (27 clinical trials in children), animals, and other studies that shed light on the mechanisms by which dyes can affect behavior.<sup>6</sup> It also includes the most comprehensive and recent exposure data on synthetic food dyes. The assessment underwent peer review and public comment.<sup>7</sup> The final 2021 OEHHA report concluded:

“The scientific literature indicates that synthetic food dyes can impact neurobehavior in some children. Data from multiple evidence streams, including epidemiology, animal neurotoxicology, *in vitro* and high throughput assays providing mechanistic insight, support this finding.”

According to the OEHHA report, examples of the neurobehavioral effects caused or exacerbated by synthetic dyes in children include hyperactivity, inattentiveness, and restlessness with some studies also reporting effects such as, sleeplessness, irritability, and aggression.<sup>8</sup> Chronic exposure to dyes may impact children’s ability to learn, succeed at school, and get along with peers on an on-going basis, with serious long-term consequences. As the OEHHA report states, “[f]or the child who is affected and their family, their teachers, and the school system, a short-term increase in inattentiveness or restlessness and anxiety that can be repeated routinely when food dye is consumed could reduce social and academic success, and is thus adverse.”<sup>9</sup> The symptoms of synthetic food dye exposure overlap with attention-deficit hyperactivity disorder (ADHD) symptoms. ADHD is associated with lifelong impairment in function and long-term outcomes that can include reduced academic achievement (e.g., failure to complete high school), substance abuse, criminality, and depression.<sup>10</sup>

Exposure to synthetic food dyes is widespread. One study found that about 90 percent of child-oriented candies, fruit-flavored snacks, and drink mixes/powders in a sampled grocery store contain synthetic food dyes.<sup>11</sup> The results of an FDA two-day exposure assessment indicate that greater than 90 percent of individuals in all populations studied, including children ages 2-5 years, consumed at least one food containing FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6.<sup>12</sup>

CDPH action is needed because federal standards do not adequately protect our children from the effects of these dyes. OEHHA’s report found that the levels of dyes considered “safe” by FDA do not adequately take neurobehavioral effects into account:

“The studies that form the basis of the US FDA... ADIs [acceptable daily intakes] ... are 35 to almost 70 years old, and as such were not capable of detecting the types

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<sup>6</sup> California OEHHA 2021.

<sup>7</sup> California OEHHA 2021. Response to Peer Review and Public Comments on the August 2020 Public Review Draft “Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes in Children.” April 2021. <https://oehha.ca.gov/media/downloads/risk-assessment/comment/rsppeerrevpubcomms040721.pdf>.

<sup>8</sup> California OEHHA, 2021, throughout, especially Chapters 2 and 5

<sup>9</sup> California OEHHA 2021, p. 174. Reiterated on p. 282.

<sup>10</sup> Erskine HE et al. Long-Term Outcomes of Attention-Deficit/Hyperactivity Disorder and Conduct Disorder: A Systematic Review and Meta-Analysis. *J Am Acad Child Adolesc Psychiatry* 2016;55(10):841-50. <https://doi.org/10.1016/j.jaac.2016.06.016>

<sup>11</sup> Batada A, Jacobson MF. Prevalence of Artificial Food Colors in Grocery Store Products Marketed to Children. *Clin Pediatr (Phila)* 2016;55(12):1113-9. <https://doi.org/10.1177/0009922816651621>

<sup>12</sup> Doell DL, Folmer DE, Lee HS et al. Exposure Estimate for FD&C Colour Additives for the US Population. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess* 2016 May; 33(5):782-797. <https://doi.org/10.1080/19440049.2016.1179536>.

of neurobehavioral outcomes assessed in later studies, or for which there is concern in children consuming synthetic dyes. The ADIs for dyes where recent data exist (Red No. 3, Red No. 40, Yellow No. 5, Yellow No. 6) would be much lower if they were based on the results of more recent animal and human studies that focus on neurobehavioral effects. Common exposures to some synthetic food dyes from foods would exceed ADIs if they were based on more recent studies focused on neurobehavioral effects.”<sup>13</sup>

Although synthetic food dyes are listed on ingredient labels of food and dietary supplement products purchased in stores, warning labels are needed since many consumers simply do not know that consuming synthetic food dyes can adversely affect neurobehavior. Warning labels, unlike the ingredient label, would enable consumers to easily and quickly make the connection between exposure to synthetic food dyes and adverse effects. Further, products sold at restaurants and similar establishments may not have ingredient lists available, making it impossible for consumers to avoid synthetic dyes in these settings.

We petition the Department to promulgate regulations requiring warning labels on foods (including beverages) and dietary supplements containing synthetic food dyes and at point of purchase, e.g., restaurant boards, as appropriate.

## **II. THE AUTHORITY FOR THE REGULATIONS.**

CDPH has authority to require warnings on foods containing color additives under two provisions of the Sherman Act. The first provision, Section 110070, authorizes CDPH to “prescribe conditions under which a color additive may be used,” and the second, Section 110100 of the California Health and Safety Code, allows the Department to “adopt additional food labeling regulations,” including safety warnings. Finally, this state authority is not preempted under federal law because the warning “concern[s]... the safety of the food or component of the food.”<sup>14</sup>

### ***(a) CDPH authority to regulate color additives under section 110070***

Statutory authority for the Department to promulgate a warning for color additives, such as the petitioners’ proposed regulation, arises from sections 110070 and 110090 of the California Health and Safety Code.

Section 110070 authorizes CDPH to “prescribe conditions under which a color additive may be used,” which may be adopted “upon the petition of any interested party.” Likewise, Section 110090, which adopts federal color additives into state law, preserves this authority for CDPH, stating, “[t]he department may, by regulation, prescribe conditions under which a color additive may be used in this state whether or not those conditions are in accordance with regulations adopted pursuant to the federal act.” Requiring warnings on foods and supplements containing synthetic dyes would be a prescribed condition under which these color additives are used.

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<sup>13</sup> California OEHHA, 2021, p. 22.

<sup>14</sup> Pub.L. No. 101-535, § 6(c)(2) (21 U.S.C. § 343-1 note).

Section 110075 of the Health and Safety Code outlines the information that petitioners must furnish to CDPH for consideration in adopting a color additive regulation. We provide this information as follows:

*i) The name and all pertinent information concerning the color additive*

Section 110075(a) requires “[t]he name and all pertinent information concerning the poisonous or deleterious substance, food additive, pesticide chemical, or color additive, including its chemical identity and composition, its proposed use, including directions, recommendations, and suggestions, its proposed labeling, and all other relevant data bearing on its physical or other technical effect, and the quantity required to produce that effect.”

Identifying information, composition, use, labeling, and associated information can be found in the U.S. Code of Federal Regulations, Title 21, Chapter 1, Subchapter A, Part 74, Subpart A, which can be accessed here (<https://www.ecfr.gov/current/title-21/part-74/subpart-A>) and has been included as an attachment.

Proposed changes to labeling requirements are outlined in section III of this petition.

*ii) The probable composition of substances formed resulting from use of the substance*

Section 110075(b) requires “[t]he probable composition of any substance formed in or on a food, drug, device, or cosmetic resulting from the use of the substance.”

We are not aware of any new substances formed in or on foods, drugs, devices, or cosmetics resulting from the use of synthetic food dyes. Methods for the detection of certified color additives in foods have also been developed by FDA and are described in articles published by FDA scientists<sup>15,16</sup> and in the OEHHA report.<sup>17</sup>

*iii) The probable consumption and effect of the substance*

Section 110075(c) requires “[t]he probable consumption and effect of the substance in the diet of man or any other animal.”

Consumption and effects of the substances are detailed in Chapters 6-8 of the 2021 OEHHA report which can be accessed here (<https://oehha.ca.gov/media/downloads/risk-assessment/report/healthfftsassess041621.pdf>) and has been included as an attachment.

*iv) Safety factors*

Section 110075(d) requires “[s]afety factors that, in the opinion of qualified experts, are generally recognized as appropriate for the use of animal experimentation data.”

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<sup>15</sup> Doell DL, Folmer DE, Lee HS et al. Exposure Estimate for FD&C Colour Additives for the US Population. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess* 2016 May; 33(5):782-797. <https://doi.org/10.1080/19440049.2016.1179536>.

<sup>16</sup> Harp BP, Miranda-Bermudez E, Barrows JN. Determination of seven certified color additives in food products using liquid chromatography. *J Agric Food Chem* 2013; 61:3726-3736. <https://doi.org/10.1021/jf400029y>

<sup>17</sup> California OEHHA 2021, p. 190

Discussion of the ADIs, no observed adverse effect levels (NOAELs), and safety factors used by FDA and why, in the opinion of qualified experts at OEHHA, they are inadequate to protect children from neurobehavioral effects of synthetic food dyes are detailed in the 2021 OEHHA report which can be accessed here (<https://oehha.ca.gov/media/downloads/risk-assessment/report/healtheffectsassessment041621.pdf>) and has been included as an attachment to this petition. This topic is covered in greater detail in Chapter 7.

v) *Practicable methods of analysis for determining identity and quantity*

Section 110075(e) requires “[p]racticable methods of analysis for determining the identity and quantity of all of the following: (1) Any substance which is in or on the food, drug, device, or cosmetic. (2) Any substance formed in or on the food, drug, device, or cosmetic because of the use of the substance. (3) The pure substance and its anticipated breakdown products and impurities.”

Currently, synthetic food dyes are batch certified by FDA using analytical chemistry methods developed for this purpose by FDA. Certification analytical methods are available from FDA. Methods for the detection of certified color additives in foods have also been developed by FDA and are described in articles published by FDA scientists<sup>18,19</sup> and in the OEHHA report.<sup>20</sup> The OEHHA report also incorporates analyses of foods, drugs, and vitamins for synthetic dyes by scientists at the University of California Davis.<sup>21</sup> We are not aware of any new substances formed in or on foods, drugs, devices, or cosmetics resulting from the use of synthetic food dyes.

vi) *Facts supporting the contention that the use of the substance will serve a useful purpose.*

The color additives described in this petition impart color and do not serve any other useful purpose.

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<sup>18</sup> Doell DL, Folmer DE, Lee HS et al. Exposure Estimate for FD&C Colour Additives for the US Population. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess* 2016 May; 33(5):782-797. <https://doi.org/10.1080/19440049.2016.1179536>.

<sup>19</sup> Harp BP, Miranda-Bermudez E, Barrows JN. Determination of seven certified color additives in food products using liquid chromatography. *J Agric Food Chem* 2013; 61:3726-3736. <https://doi.org/10.1021/jf400029v>

<sup>20</sup> California OEHHA 2021, p. 190

<sup>21</sup> California OEHHA 2021, p. 232-244 and Appendix E.

***(b) CDPH authority to require warnings on foods under section 110100***

Separate from its authority over color additives, CDPH also has authority to require warnings on foods under section 110100 of the California Health and Safety Code, which allows the Department to “adopt additional food labeling regulations” beyond the federal Food, Drug, and Cosmetics Act (FDCA). The code also authorizes CDPH to require disclosures when needed to prevent the labeling of a food from being misleading. CDPH previously cited this provision in requiring warnings concerning gastrointestinal risks on foods and dietary supplements containing aloe vera and certain other laxative ingredients.<sup>22</sup>

CDPH’s authority to require disclosures to prevent misleading labeling stems from section 110290, which states that the extent to which a label “fails to reveal facts concerning the food...or consequences of customary use” will be considered in determining whether the labeling or advertisement of a food is misleading. Under section 110660, a food is misbranded “if its labeling is false or misleading in any particular,” and the sale of misbranded food is prohibited under sections 110760, 110765, and 110770.

Without warnings, food and supplement labels for products containing synthetic dyes fail to reveal a material fact, i.e., the known health risks that result of their customary use, as established by the 2021 OEHHA report. To ensure these products are not misbranded, CDPH should require warnings in a manner prescribed in this petition.

Finally, section 110705 provides the statutory authority for the formatting of the warning disclosure placed on laxative ingredients.<sup>23</sup> We have asked CDPH to adopt by reference those same formatting requirements for the warnings requested in this petition.

***c) CDPH authority to regulate food additives and require warnings is not preempted by federal law***

The warnings requested in this petition are not expressly preempted by the FDCA. While the Nutrition Labeling Education Act (NLEA) amended the FDCA with a provision expressly preempting “any requirement for nutrition labeling of food,” a safety warning related to a color additive—a non-nutritive ingredient—is not a nutrition labeling requirement and is therefore not subject to NLEA.<sup>24</sup> Moreover, the NLEA specifically provides that the express preemption provision “shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.”<sup>25</sup> The safety warning we have requested is thus clearly exempted from the express preemption provision of the NLEA.

Likewise, the warnings are not field preempted because the NLEA included a savings clause stating that the law “shall not be construed to preempt any provision of State law, unless such

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<sup>22</sup> Cal. Code Regs. tit. 17, § 10750.

<sup>23</sup> Cal. Code Regs. tit. 17, § 10750. Available at [https://govt.westlaw.com/calregs/Document/IB2C7E1E35A2011EC8227000D3A7C4BC3?viewType=FullText&originationContext=documentto c&transitionType=CategoryPageItem&contextData=\(sc.Default\)&bhcp=1](https://govt.westlaw.com/calregs/Document/IB2C7E1E35A2011EC8227000D3A7C4BC3?viewType=FullText&originationContext=documentto c&transitionType=CategoryPageItem&contextData=(sc.Default)&bhcp=1).

<sup>24</sup> See *Sciortino v. PepsiCo, Inc.*, 108 F. Supp. 3d 780 (N.D. Cal. 2015) (holding that a notice for caramel coloring required under California Proposition 65 was not preempted because it was not related to nutrition).

<sup>25</sup> Pub.L. No. 101-535, § 6(c)(2) (21 U.S.C. § 343-1 note).

provision is expressly preempted.”<sup>26</sup> Finally, the warnings are not preempted through conflict preemption because there is no conflict between the state warning and federal rules authorizing the use of color additives.<sup>27</sup>

### III. PROPOSED DRAFT OF REGULATION SECTION 10751

Petitioners respectfully propose and request the regulation in this section to require warning labels that are derived and condensed from the wording used in OEHHA’s press release regarding the finalization of their assessment.<sup>28</sup> This proposed regulation is largely modeled after 17 CCR § 10750, which requires warnings for foods and supplements that contain laxatives.

The following proposed Section 10751 should be added to Title 17, Article 3 of the California Code of Regulation (underline indicates added text):

#### §10751. Labeling of Foods and Supplements Containing Certain Synthetic Food Dyes

(a) Any food or dietary supplement, as defined in Title 17, California Code of Regulations, Division 1, section 10200, that contains any amount of FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6, shall comply with the following:

(1) The label of foods and dietary supplements that have a total surface area available to bear labeling of 12 square inches or more shall bear the following warning on its principal display panel, as defined in Section 110015 of the California Health and Safety Code, in the manner prescribed in paragraph (a)(2) of section 10750:

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

(2) Foods and dietary supplements in small packages that have a total surface area available to bear labeling of less than 12 square inches shall include the warning required by paragraph (a)(1) of this section in a package insert or a tag attached to the package in the manner prescribed in paragraph (a)(2) of section 10750.

(4) Unpackaged, bulk foods or dietary supplements shall bear the warning required by paragraph (a)(1) of this section on the shelf or bin where the food is displayed for retail sale in the manner prescribed in paragraph (a)(2) of section 10750.

(5) Foods sold in restaurants shall place an icon adjacent to each menu item name to indicate that the item contains synthetic food dyes and shall place the following warning language on their menus and menu boards. Both the icon and warning statement shall be the same size and color as the largest menu item name.

<sup>26</sup> 21 U.S.C. § 343-1. Sciortino v. PepsiCo, Inc., 108 F. Supp. 3d 780 (N.D. Cal. 2015) (“The NLEA’s savings clause reflects that Congress “disavow[ed] any implied preemption.”)

<sup>27</sup> Cf. Sciortino v. PepsiCo, Inc., 108 F. Supp. 3d 780 (N.D. Cal. 2015) (carmel coloring warnings are not preempted by FDA’s finding that the additive was safe under federal law).

<sup>28</sup> “A state report released today finds that consumption of synthetic food dyes can result in hyperactivity and other neurobehavioral problems in some children, and that children vary in their sensitivity to synthetic food dyes.” California Office of Environmental Health Hazard Assessment. *Report Links Synthetic Food Dyes to Hyperactivity and other Neurobehavioral Effects in Children.* April 16, 2021. <https://oehha.ca.gov/risk-assessment/press-release/report-links-synthetic-food-dyes-hyperactivity-and-other>.



*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*

(6) The warning required by paragraph (a)(5) of this section shall be prominently placed on the menu or menu board so as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase and use.

(B) This section does not apply to an alcoholic beverage, as defined in Section 23004 of the Business and Professions Code, or a medical food, as defined in California Health and Safety Code § 109971.

Pursuant to California Government Code 11340.7, please respond to this petition within thirty days.

All studies and documents cited in this petition are attached.

Thank you in advance for your consideration. If you have any questions or comments, please contact Jensen N. Jose, our agent on this petition, at [jjose@cspinet.org](mailto:jjose@cspinet.org) and copy Thomas M. Galligan ([tgalligan@cspinet.org](mailto:tgalligan@cspinet.org)) on all responses.

Respectfully submitted:

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