

May 12, 2023

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Dear Dr. Aragón:

The Center for Science in the Public Interest (CSPI) thanks the California Department of Public Health (CDPH or the Department) for the opportunity to testify at the April 11, 2023 [hearing](#) on our petition ([P-22-001](#)) that seeks to require warning labels on all foods and dietary supplements that contain synthetic food dyes sold in California. The undersigned respectfully submit this comment to supplement our oral testimonies and further support our petition.

Specifically, this comment:

- I. Presents survey data showing that Californians overwhelmingly want and need synthetic food dye warnings.
- II. Addresses food industry mischaracterizations of the health effects assessment finalized by the California Office of Environmental Health Hazard Assessment (OEHHA) in 2021 at the April 11 hearing.
- III. Describes how the requested warnings are permissible compelled speech under the First Amendment.

**I. Californians Overwhelmingly Want and Need Synthetic Dye Warnings**

Synthetic food dye warnings are something Californians want and need, according to an online survey of 1,008 Californian adults commissioned by CSPI.<sup>1</sup> The survey assessed frequency of reviewing food ingredient labels, familiarity with the health effects associated with synthetic food dyes, ability to identify synthetically dyed foods based on appearance without ingredient or warning labels, and support for requiring warning labels on synthetically dyed foods.

There was a high degree of support for mandatory warning labels on synthetically dyed foods among survey respondents, and the level of support was consistently high across all sociodemographic stratifications we examined. When asked, “Do you think foods containing synthetic food dyes in the U.S. should be required to have a warning label on the front of the package?” 71.1% ( $\pm 2.8\%$  [95% confidence interval]) of respondents said “yes,” 13.3% ( $\pm 2.1\%$ ) said “no,” and 15.6% ( $\pm 2.2\%$ ) said “I don’t know.” We examined whether the level of support differed across important sociodemographic stratifications and found the overwhelming majority of respondents within each stratum selected “yes.” Specifically, in Table 1 we list the proportion of respondents selecting “yes” within specific sociodemographic groups (range: 66.7%-78.0%).

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<sup>1</sup> Our survey was carried out by an independent third party in December of 2021, and was generally representative of the population of California with some deviations (see Appendix, Table A1).

**Table 1.** Support for mandatory warning labels among survey respondents by sociodemographic characteristics.

<b>Sociodemographic Characteristic</b>	<b>Groups</b>	<b>Proportion supportive of mandatory synthetic dye warning labels</b>
Children at home	Children present in home	78.0% ( $\pm$ 4.3%)
	No children present in home	67.3% ( $\pm$ 3.6%)
Educational attainment	High school or less	69.3% ( $\pm$ 6.8%)
	Some college/two-year technical college/technical school	68.6% ( $\pm$ 4.8%)
	Four-year college degree or more	73.7% ( $\pm$ 3.9%)
Household income in 2020	<\$50,000	69.0% ( $\pm$ 4.8%)
	\$50,000 to <\$100,000	74.4% ( $\pm$ 5.3%)
	$\geq$ \$100,000	70.9% ( $\pm$ 4.5%)
Racial/ethnic identification	Hispanic	72.7% ( $\pm$ 4.9%)
	Non-Hispanic Black	72.4% ( $\pm$ 11.5%)
	Non-Hispanic Other	70.8% ( $\pm$ 8.1%)
	Non-Hispanic White	70.1% ( $\pm$ 4.0%)
Political party affiliation	Democrat	73.3% ( $\pm$ 3.9%)
	Independent	69.5% ( $\pm$ 6.2%)
	Republican	68.9% ( $\pm$ 6.2%)
	“Something else”	69.4% ( $\pm$ 15.0%)
	“Not sure”	66.7% ( $\pm$ 16.9%)
	Declined to answer	68.2% ( $\pm$ 19.5%)

It is clear from these results that there is broad support for warning labels among Californians across the spectrum of sociodemographic identities, including political affiliation.

After reading the following statement,

A California government agency has concluded that “synthetic food dyes can impact neurobehavior in some children.” In Europe, warning labels are required on foods containing certain synthetic food dyes that say that the dyes “may have an adverse effect on attention and activity in children.”

the proportion of total survey respondents supportive of mandatory warning labels increased to 84.6% ( $\pm$  2.2%), which underscores the importance of educating consumers about synthetic dyes, which the proposed warning is designed to do.

Opponents may argue that warning labels are redundant with ingredient labeling, but we suspect consumers will only check ingredient labels for synthetic dyes if they know beforehand that these dyes are hazardous. While 64.6% ( $\pm$  3.0%) of respondents correctly reported that synthetic

food dyes do not offer health benefits, only 44.6% ( $\pm 3.1\%$ ) of respondents were aware that synthetic dyes can cause or worsen hyperactivity and/or inattention. Therefore, the majority of Californians would benefit from having this information appear prominently on food packaging and menus. This benefit may be especially pronounced in subpopulations where awareness is even lower, such as in those with a high school diploma or less, of whom only 33.5% ( $\pm 7.0\%$ ) were aware of the neurobehavioral effects of synthetic dyes compared to 46.2% ( $\pm 5.2\%$ ) of those who completed some college, two-year college, or technical school and 47.6% ( $\pm 4.5\%$ ) of those who completed a four-year college degree or more.

Checking ingredients for every food purchased in every store and restaurant requires a substantial and ongoing investment of time and effort, which is an unreasonable burden to place on consumers. Our survey found that less than one-third of survey respondents (28.6%  $\pm 2.8\%$ ) reported that they always read ingredient labels, while the majority of survey respondents (64.3%  $\pm 3.0\%$ ) sometimes read ingredient labels and 7.1% ( $\pm 1.6\%$ ) never read ingredient labels. Groups in which use of ingredient labels is especially uncommon may benefit most from warnings. This would include people with lower levels of educational attainment (11.4%  $\pm 4.7\%$  of those with a high school diploma or less never read ingredient labels, compared to 3.5%  $\pm 1.7\%$  of those who completed a four-year college degree or more) or a lower household income (10.6%  $\pm 3.2\%$  of those with a household income less than \$50,000 never read ingredient labels compared to 3.1%  $\pm 1.7\%$  of those with a household income greater than \$100,000). Overall, it is clear that Californians do not always read ingredient labels, and consequently, that ingredient labeling alone is inadequate to protect Californian children from synthetic dyes.

Our survey also revealed clear misperceptions about which foods contain synthetic dyes: over one-third of respondents (34.6%  $\pm 2.9\%$ ) believed they could tell whether a food contained a synthetic dye based on its color, while 44.0% ( $\pm 3.1\%$ ) believed they could not identify synthetic dye-containing foods by color and 21.3% ( $\pm 2.5\%$ ) were unsure. However, when shown images of products containing synthetic dyes, there was wide variation in respondents' ability to identify which ones contained synthetic dyes, from 19.4% ( $\pm 2.4\%$ ) accurately identifying that Mt. Olive pickles<sup>2</sup> contained synthetic dyes to 88.2% ( $\pm 2.0\%$ ) identifying that M&Ms contained synthetic dyes (both products contain synthetic dyes).

Overall, our survey results demonstrate that the majority of Californians, regardless of educational attainment, household income, race/ethnicity, and political party affiliation, want and will benefit from warning labels that empower them to make more informed choices about their synthetic food dye consumption.

## **II. Mischaracterizations of the OEHHA Health Effects Assessment**

At the April 11<sup>th</sup>, 2023 hearing, individuals representing the food industry and color manufacturers made inaccurate and misleading statements regarding the OEHHA health effects assessment. We offer corrections and clarifications to those statements below.

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<sup>2</sup> Mt. Olive Baby Kosher Dills contain FD&C Yellow No.5 according to product label images found on the manufacturer website. <https://www.mtolivepickles.com/pickle-products/kosher-baby-dills/>. Accessed: May 10, 2023.

### *(1) OEHHA Established Causality*

An industry representative stated that OEHHA did not establish causality between synthetic dyes and neurobehavioral problems, which is not the case.

Specifically, Sarah Codrea, representing the International Association of Color Manufacturers (IACM) stated in her testimony at 30 min 32 seconds, “Therefore, [OEHHA] could not conclude that there is any causal relationship between FD and C colors and negative behavior.”

This statement is false. In the introduction to Chapter 7 (“Risk Characterization”) of OEHHA’s health effects assessment, OEHHA states: “Based on multiple streams of evidence, the FD&C synthetic food dyes **cause or exacerbate** neurobehavioral problems in children” [emphasis added].<sup>3</sup> In the introduction to Chapter 8 (“Overall Summary and Conclusions”), OEHHA uses nearly identical language, stating, “The scientific literature provides evidence in humans and animals, as well as mechanistic information, that synthetic food dyes can **cause or exacerbate** neuro-behavioral problems in some children” [emphasis added].<sup>4</sup> As such, a causal linkage between synthetic food dyes and adverse neurobehavioral effects has been clearly established and explicitly stated by OEHHA. Additionally, OEHHA directly addressed this in response to comments received from IACM, saying:<sup>5</sup>

The epidemiologic literature we emphasize is comprised of human clinical trials that used a crossover blinded design. These can be interpreted to provide strong evidence of causality by the nature of their design. We present a thorough evaluation of the human, animal, and in vitro studies available and synthesize the information. Together the available information supports that food dyes have neurobehavioral effects in some children.

### *(2) OEHHA Characterized Risk*

An industry representative stated that OEHHA only conducted a hazard assessment, as opposed to a risk assessment.

Specifically, Sarah Codrea of IACM stated at 30 min, 4 sec, “After a 2018 budget request for [OEHHA] to conduct a risk assessment, OEHHA published a hazard assessment in 2021, a distinction worth noting. A hazard assessment identifies potential sources of harm, while a risk assessment assesses the possibility that harm will occur. So while the [OEHHA] assessment concluded, there may be potential for [FD&C] colors to cause adverse behavioral outcomes, it did not and could not... assess the likelihood of those outcomes to occur.”

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<sup>3</sup> California Office of Environmental Health Hazard Assessment. Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes in Children. April 2021. p. 246. <https://oehha.ca.gov/media/downloads/risk-assessment/report/healtheffectsassess041621.pdf>. Accessed April 13, 2023.

<sup>4</sup> *Id.* p. 279.

<sup>5</sup> California Office of Environmental Health Hazard Assessment. Response to Peer Review and Public Comments on the August 2020 Public Review Draft “Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes on Children.” April 2021. p. 41. Available: <https://oehha.ca.gov/media/downloads/risk-assessment/comment/rsppeerrevpubcomms040721.pdf>. Accessed May 8, 2023.

This statement is misleading. While OEHHA did not estimate the statistical probability of adverse outcomes, it did characterize risk posed by synthetic dyes by comparing estimated exposures to the Acceptable Daily Intakes (ADIs) set by the US Food and Drug Administration (FDA) and Joint FAO/WHO Expert Committee on Food Additives (JECFA) for the dyes, in a chapter titled “Risk Characterization.”

OEHHA described its approach to risk characterization as follows:<sup>6</sup>

To characterize the risk for neurobehavioral effects following food dye exposure, OEHHA first compared the US FDA ADIs and the NOAELs [no observed adverse effect levels] from which they were derived against NOAELs from the studies reviewed in Chapter 3, Animal Toxicology. Next we compared the estimated food dye exposures, described in Chapter 6, from food consumption and exposures from over-the-counter medicines and vitamins to available regulatory benchmarks in a traditional Hazard Index approach for noncancer health effects. The Hazard Index approach divides estimated exposures by a toxicity benchmark. If that ratio is greater than 1, then it is indicative of a possible risk of adverse noncancer effects.

The benchmarks used by OEHHA were the FDA and JECFA ADIs. As such, a hazard index value >1 means that estimated exposure exceeds the FDA- or JECFA-determined acceptable level of exposure.

OEHHA found that generally hazard indices were <1, with the exception of some of those for Red 3. However, it must be noted that none of the existing ADIs were based on neurobehavioral effects, meaning hazard indices <1 are not sufficient to dismiss the potential risk of adverse neurobehavioral outcomes.<sup>7</sup> Indeed, OEHHA determined that ADIs would likely be much lower if they were based on adverse neurobehavioral effects, and that exposures to synthetic dyes from food would likely exceed these more protective ADIs. Specifically, OEHHA said:<sup>8</sup>

A number of animal studies of single synthetic food dyes and a dosing regimen that included in utero, postnatal and juvenile exposures found evidence of effects on behavior in the offspring. A handful of these studies observed effects at doses lower than the NOAELs used by the FDA to derive their ADIs. Almost all the studies in mature animals that measured behavioral changes and/or changes in the brain found effects of the synthetic food dyes at doses lower than the NOAELs used by the US FDA for the derivation of the ADIs. A number of these studies observe effects on behavior in animals at doses close to or even lower than the existing FDA ADIs...For several dyes, if ADIs were based on more modern studies that observed neurobehavioral effects, those ADIs would be considerably lower. We note this for Red No. 3 and Red No. 40 based on animal studies. Applying such ADIs explicitly for neurobehavioral effects would result in likely exceedances from food and some OTC medications.

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<sup>6</sup> *Supra*, OEHHA Health Effects Assessment. p. 246.

<sup>7</sup> “Note that none of the ADIs are based on neurobehavioral effects observed in animals or humans. Thus, the [hazard index] may not be applicable to nor adequate to describe risks for neurobehavioral changes” *Id.* p.258

<sup>8</sup> *Id.* p. 277.

Thus, OEHHA found that current exposures to synthetic dyes likely exceed the levels that would be considered protective against neurobehavioral effects in children, meaning consumers are likely at risk of experiencing adverse neurobehavioral effects from dyes.

This is especially the case for the synthetic dye Red 3. OEHHA found that 95<sup>th</sup> percentile exposure to Red 3 among children under 2 years old exceeds the existing FDA ADI, which is not based on neurobehavioral effects,<sup>9</sup> with hazard ratios of 1.93 and 3.16 in the typical and high exposure scenarios, respectively.<sup>10</sup> Further, in both typical and high exposure scenarios, mean and 95<sup>th</sup> percentile exposures to Red 3 for some age ranges exceed the ADI established by JECFA with hazard ratios ranging from 1.02 to 79.<sup>11</sup> These findings indicate that consumers are currently at risk of harm from Red 3. If the current ADI were revised, as OEHHA suggests, the hazard ratios for Red 3 may be even greater because reducing the ADI (which OEHHA expects would happen upon revisiting the current ADI) without changing exposure would inherently increase the hazard index, meaning the risk is likely higher than that estimated from the current ADI.

As another example, FDA's ADI for Yellow 5 is more than 60 times higher than the level that OEHHA and researchers identified as triggering neurobehavioral effects in a double-blinded, placebo-controlled study of young children.<sup>12,13,14</sup> OEHHA's assessment found that children under 16 years old consume enough Yellow 5 each day to meet or exceed the minimum dose that triggered adverse neurobehavioral effects in that study.<sup>15,16</sup>

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<sup>9</sup> *Supra*, OEHHA Health Effects Assessment. p. 248. "The current US FDA ADI for Red No. 3 of 2.5 mg/kg bw/day was approved in 1969 and was based on a two-year study in rats and supported by a two-year study in dogs...conducted at FDA by Hansen from 1952-1954. The study used doses of 0.5, 1.0, 2.0 and 5.0 % Red No. 3 in the diet fed to 12 male and 12 female rats per dose group and 3 male and 3 female dogs per dose group...The NOAEL used for the ADI was 0.5% in the diet in rats, estimated as a dose of 250 mg/kg/day, based on observation of "distended cecum" at 1.0% in the diet. There was also decreased body weight at 2% in the diet in rats. There were some pathological findings in dogs that US FDA viewed as not treatment-related minor incidental abnormalities. FDA derived the ADI of 2.5 mg/kg/day by dividing the NOAEL in the rat study by 100."

<sup>10</sup> *Id.* at p. 264 (*see* Table 7.6).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 274.

<sup>13</sup> Rowe KS, Rowe KJ. Synthetic food coloring and behavior: A dose response effect in a double-blind, placebo-controlled, repeated-measures study. *J Pediatr.* 1994;125(5 Pt 1):691-698

<sup>14</sup> Rowe and Rowe (1994) conducted a double-blinded, placebo-controlled trial testing the behavioral effects of multiple doses of Yellow No. 5 (0.1, 2, 5, 10, or 20 mg) in children (over half of whom did not have behavioral problems) and used a validated behavior test to measure the response. They found that behavior scores were significantly different in children on days they had received the dye versus when they received the placebo. Additionally, the higher the dose of dye, the worse the children scored. This kind of dose-response is strong evidence of a true effect. The mean behavior score difference between the group of children who reacted to dyes and the group that did not was statistically significant at doses of 2 mg and higher. The average age of participants was seven years old. Based on a reference body weight of 25.5 kg for a 7-year-old child, 2 mg of Yellow No. 5 is equivalent to a dose of 0.08 mg/kg-body weight/day. The ADI set by the FDA for Yellow No. 5 is 5 mg/kg-body weight/day, 62.5 times higher than the level identified by Rowe and Rowe that produced neurobehavioral effects in children.

<sup>15</sup> *Supra*, OEHHA Health Effects Assessment. Table 6.1.1. p. 214.

<sup>16</sup> As calculated above, the minimum triggering dose of Yellow 5 identified by Rowe and Rowe (1994) was 0.08 mg/kg bw/day. Under the typical exposure scenario, mean two-day average exposures for children aged 0 to 16

Therefore, OEHHA determined that synthetic dyes likely pose a risk to consumers at current levels of exposure. Additional work would be needed to express risk in probabilistic terms, but contrary to assertions by IACM, OEHHA did not simply perform a hazard assessment.

### *(3) Peer Reviewers Were Supportive of the OEHHA Report and its Conclusions*

Industry representatives implied that one peer reviewer of the draft OEHHA assessment, Dr. Peter Spencer, was unsupportive of OEHHA's conclusions, which is not the case. Robinan Gentry, a paid consultant to the American Beverage Association (ABA), said in her testimony at the hearing (24 min, 28 sec), "The [OEHHA assessment] was subjected to peer review by experts from the University of California and one of the peer reviewers, a neurotoxicology expert[,] raised general concerns consistent with those in our assessment regarding uncertainty of test article purity, the inability of selected studies in animals to provide biological plausibility for effects in humans, and the lack of scientific support of a [OEHHA's] conclusions that suggested behavioral changes in animals are the result of neurosis." This comment is seemingly in reference to Dr. Spencer's review, as he is described in that review as, "a university-based, neuroscience-trained neurotoxicologist with decades of experience studying human and/or animal responses to exposure to chemicals/metabolites present in or added to food, and to exposure to various drugs, workplace and environmental chemicals with neurotoxic potential."<sup>17</sup>

Dr. Gentry's statement mischaracterizes the nature of Dr. Spencer's review. While his review does include critiques of OEHHA's assessment, as should be expected in any scientific peer-review, his summarized findings state, "Nevertheless, in general, this reviewer agrees with the broad conclusion that ingestion of food dyes may reversibly modify behavior in the short-term, which has special relevance to susceptible children in the context of Attention Deficit Hyperactivity Disorder." Furthermore, Dr. Spencer's summary assessment of the report conclusions states:

**The Reviewer supports the general conclusion** [that] "The scientific literature provides evidence in humans and animals, as well as mechanistic information, that synthetic food dyes may cause or exacerbate neurobehavioral problems in some children. Data from multiple evidence streams, including epidemiology, animal neurotoxicology, in vitro and high throughput assays providing mechanistic insight, taken together, provide support that some FD&C batch-certified synthetic food dyes impact neurobehavior in children. More evidence is currently available for Red No. 3, Red No. 40, and Yellow No. 5 than the other FD&C batch certified dyes." [*emphasis in original*]

As such, it is clear that Dr. Spencer was supportive of OEHHA's conclusions.

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ranged from 0.07 to 0.12 mg/kg bw/day, and under the high exposure scenario, mean two-day average exposure for children aged 0 to 16 ranged from 0.12 to 0.19 mg/kg bw/day. Further, 95<sup>th</sup> percentile two-day average exposures across both the typical and high exposure scenario ranged from 0.26 to 0.76 mg/kg bw/day in children under 16 years old.

<sup>17</sup> Spencer, P. Peter Spencer Peer Review Comment on Draft Health Effects Assessment. November 9, 2020. Available: <https://oehha.ca.gov/media/downloads/risk-assessment/peer/peterspencerfooddypeerreview.pdf>.



(4) *OEHHA has Addressed the American Beverage Association-Funded Assessment by Gentry et al.*

In oral testimony, an industry representative cited an industry-funded assessment—which has been directly rebutted by OEHHA—as evidence that synthetic dyes are not harmful. Specifically, Robinan Gentry, a paid ABA consultant, provided testimony summarizing findings from a 2021 publication on which she was the lead author. This publication was funded by the ABA, and asserted, as summarized by Gentry in her testimony (at 23 min, 52 seconds), “Overall, the results of our assessment indicated a lack of adequate or consistent evidence of neurological effects supported by lack of bioavailability and brain penetration predicted by the [in silico] assessment. It also indicated a lack of evidence to support key events and adverse outcome pathways associated with neurodevelopmental effects, thereby supporting a lack of biological plausibility.”

The assertions in Gentry et al.’s paper have been thoroughly addressed by OEHHA in a letter to the editor.<sup>18</sup> OEHHA’s rebuttal highlights several critical errors, oversights, and misrepresentations made by Gentry et al. Most notably, OEHHA correctly points out that Gentry et al. excluded all 27 human clinical trials considered by OEHHA. These clinical trials provided the strongest evidence that synthetic food dyes cause neurobehavioral problems in children.<sup>19</sup> We urge CDPH to take OEHHA’s letter under careful consideration while reviewing the testimony and any comments provided by Gentry and other representatives of the food and color industries.

We also note that Gentry et al. in turn replied to OEHHA’s letter with their own letter to the editor to clarify some points, including stating that they excluded human clinical trials from their assessment, “largely because animal studies traditionally are the basis for toxicological assessments when there is a lack of and/or unreliable human data.”<sup>20</sup> There is not a lack of reliable human data on the effects of synthetic food dyes on neurobehavior. Further, OEHHA considered the animal and in vitro evidence alongside the human clinical trial evidence, integrating all three evidence streams into its final conclusion. Gentry et al. also stated they excluded the human clinical trial data in part because, “others were conducting a review of the human clinical trials in parallel,”<sup>21</sup> citing Llewellyn et al. (2020).<sup>22</sup> Llewellyn et al. is an industry-funded<sup>23</sup> non-systematic review with a limited scope and unclear exclusion criteria

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<sup>18</sup> Miller MD, Golub MS, Marty MA. Gentry et al. (2021) integration of evidence to evaluate the potential for neurobehavioral effects following exposure to USFDA-approved food colors. *Food Chem Toxicol.* 2021 Jun;152:112211. doi: 10.1016/j.fct.2021.112211. Epub 2021 Apr 26. PMID: 33915229. Available: <https://www.sciencedirect.com/science/article/pii/S0278691521002441>.

<sup>19</sup> *Supra*, OEHHA Response to Peer Review and Public Comments. p. 110 (OEHHA stated, “As regards causality, the epidemiologic literature we emphasize is comprised of human clinical trials that used a cross-over blinded design. These can be interpreted to provide strong evidence of causality by the nature of their design.”).

<sup>20</sup> Gentry R, Rodricks J, Clewell H, Greene T, Chappell G, Lea I, Borghoff S, Yang C, Rathman J, Ribeiro JV, Hobocienski B, Mostrag A. RE: Response to the Office of Environmental Health Hazard Assessment on comments related to Gentry et al. (2021). *Food Chem Toxicol.* 2021 Jun;152:112202. doi: 10.1016/j.fct.2021.112202. Epub 2021 Apr 17. PMID: 33872725. Available: <https://www.sciencedirect.com/science/article/pii/S0278691521002350>.

<sup>21</sup> *Id.*

<sup>22</sup> Llewellyn, GC, Penberthy JK, Parker JM. Food Color Additives in the US Food Supply: Review of Neurobehavioral Safety (2020). *Journal of Pediatric Neurology and Neuroscience.* 4(1): 55–72. DOI: 10.36959/595/409.

<sup>23</sup> The Acknowledgement section of Llewellyn et al. states, “The funding sponsor of this research is the International



which, as a result, is of very limited utility relative to OEHHA’s comprehensive systematic review. Llewellyn et al. conducted literature searches to identify human clinical studies published between 2017 and 2019 or systematic reviews and meta-analyses published in any year. Their searches returned 44 records, but only six of these were included in the final assessment based on the application of poorly defined inclusion and exclusion criteria.<sup>24</sup> Two additional human studies were identified separately. As such, Llewellyn et al. considered eight human studies, systematic reviews, or meta-analyses, compared to the OEHHA assessment that considered 27 human clinical trials and one meta-analysis. Thus, OEHHA’s critique of Gentry et al. regarding their exclusion of human clinical trials is not resolved by considering the assessment by Llewellyn et al. Overall, OEHHA’s 2021 health effects assessment stands as the most comprehensive and authoritative review of the evidence to date (see Section III(1) below for further details).

### **III. Proposed Warnings are Permissible Compelled Speech under the First Amendment**

The proposed warnings are constitutional as the warnings meet the three-pronged First Amendment test for compelled speech, which was first laid out by the Supreme Court in *Zauderer v. Office of Disciplinary Council of Supreme Court*.<sup>25</sup> The First Amendment affords limited protection to commercial free speech (speech concerning the potential sale of a consumer good).<sup>26</sup>

When the government requires a disclosure in the commercial context, such as the warnings at issue here, the Supreme Court’s test in *Zauderer* requires the disclosure be (1) strictly factual and uncontroversial, (2) reasonably related to a legitimate government interest, and (3) not unjustified or unduly burdensome.<sup>27</sup> The proposed warning meets each of these requirements.

#### *(1) The Warnings are Strictly Factual and Uncontroversial*

“Factual and uncontroversial” information is not opinion-based<sup>28</sup> or subjective.<sup>29</sup> Regarding “uncontroversial” specifically, the information should be factually accurate<sup>30</sup> and

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Association of Color Manufacturers (IACM). Authors Llewellyn and Parker are employed by Toxicology Regulatory Services, Inc. (TRS), consultants to IACM, the research sponsor. Author Penberthy is employed by the University of Virginia School of Medicine and received funding from IACM for her contribution to this manuscript. IACM reviewed the draft manuscript, however, the manuscript authors were not required to accept sponsor comments.”

<sup>24</sup> The Methods section of Llewellyn et al. states, “The titles and abstracts, if applicable, of the returned records in all searches were then evaluated to determine their relevance for inclusion within this evaluation. The inclusion criteria were full-length articles in a peer reviewed journal; written in English; relevant to the respective search. Scientific discretion was used to determine if the titles, and abstracts, if available, were relevant given the search terms and objective of the search. These criteria led to the final selection of 12 manuscripts in the animal literature and 6 manuscripts in the human literature for further review.”

<sup>25</sup> *Zauderer v. Office of Disciplinary Council of Supreme Court*, 471 U.S. 626, 651 (1985).

<sup>26</sup> *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447 (1978).

<sup>27</sup> *Zauderer*, 471 U.S. at 651 (1985).

<sup>28</sup> *Zauderer*, 471 U.S. at 651.

<sup>29</sup> *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012); *Entm’t Software Ass’n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006).

<sup>30</sup> *Am. Meat Inst. v. United States Dep’t of Agric*, 760 F.3d 18, 27 (DC Cir. 2014).

nonideological.<sup>31</sup>

Statements consistent with expert and government opinion are more likely to be found uncontroversial. For example, in *CTIA - The Wireless Ass'n v. City of Berkeley*, the Ninth Circuit found that a safety warning regarding radiation emitted by cell phones was strictly factual and uncontroversial because it was literally true and not misleading. The Court found that alignment between mandated warnings and federal statements was evidence that the warning was not controversial.<sup>32</sup> Conversely, in *Cal. Chamber of Commerce v. Council for Educ. & Rsch. on Toxics*, an OEHHA warning for acrylamide was found not strictly factual and uncontroversial because the federal FDA had cautioned that the warning might be misleading and OEHHA had not independently confirmed the factual basis for the warning.<sup>33</sup>

As in *CTIA*, the petition proposes warnings that are literally true:

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*<sup>34</sup>

These warnings are literally true as they merely describe a conclusion that was reached by the state of California.

In addition to the warnings being literally true, OEHHA's conclusion is accurate, nonideological, and based on the agency's independent objective systematic review of the scientific evidence. It represents the most comprehensive and rigorous assessment undertaken to date of the relationship between synthetic dyes and effects on child neurobehavior.<sup>35</sup> OEHHA affirmed this fact in its response to peer reviewer and public comments:

As regards other reviews of the information, OEHHA's review was more inclusive and rigorous...As we describe in the Introduction, OEHHA did not limit the review to the question of effects on children diagnosed with ADHD or other behavioral disorders. Rather, OEHHA evaluated the epidemiological literature to determine whether there might be any effects on behavior of the FD&C batch-certified synthetic food dyes in children in the general population with or without a diagnosis of ADHD. We did not focus solely on effects related to activity and attention, but evaluated the literature for

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<sup>31</sup> *Am. Bev. Ass'n v. City and Cty of San Francisco*, 871 F.3d 884 (9th Cir. 2017).

<sup>32</sup> *CTIA - The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 847 (9th Cir. 2019)

<sup>33</sup> *Cal. Chamber of Commerce v. Council for Educ. & Rsch. on Toxics*, 29 F.4th 468 (9th Cir. 2022)

<sup>34</sup> CSPI. *Petition for Rulemaking to Implement Warning Labels on Food Products and Dietary Supplements that Include Certain Synthetic Food Dyes*. December 8, 2022. P. 1-2.

<sup>35</sup> CSPI. *Petition for Rulemaking to Implement Warning Labels on Food Products and Dietary Supplements that Include Certain Synthetic Food Dyes*. December 8, 2022. P. 3.

effects on other neurobehavioral impacts as well. In addition, OEHHA evaluated the animal toxicology literature relevant to neurological endpoints; these studies were not emphasized in the 2011 US FDA review (US FDA, 2011). There is no documentation that is publicly available that the FDA (or JECFA or EFSA for that matter) reviewed the animal literature as thoroughly as did OEHHA...we reviewed newer data relevant to mechanisms of action of potential neurobehavioral or neurotoxic effects of the food dyes. The authoritative bodies cited in the comment did not review and integrate all the mechanism, animal toxicology and human studies on the topic of neurotoxicity. In short, OEHHA did a more thorough review of more scientific information than any of the international bodies noted in the comment.<sup>36</sup>

Likewise, OEHHA's findings accord with federal agency findings as FDA acknowledged that synthetic dyes can impact children's neurobehavior. The OEHHA report itself stated, "This conclusion is, in fact, not different from the FDA's conclusion that some children appear to be sensitive to food dyes."<sup>37</sup> In a 2011 assessment, FDA concluded, "For certain susceptible children with Attention Deficit/Hyperactivity Disorder [(ADHD)] and other problem behaviors...the data suggest that their condition may be exacerbated by exposure to a number of substances in food, including, but not limited to, synthetic color additives."<sup>38</sup> In 2018, FDA stated, "most children have no adverse effects when consuming foods containing color additives, but some evidence suggests that certain children may be sensitive to them."<sup>39</sup>

Other expert bodies have also determined that synthetic dyes can impact neurobehavior. The American Academy of Pediatrics (AAP) has declared artificial food colors to be "compounds of concern" because "[a]rtificial food colors may be associated with exacerbation of attention-deficit/hyperactivity disorder symptoms [(ADHD)]."<sup>40</sup> In a 2018 technical report, AAP noted the FDA's original safety approvals for the color additives are based on animal studies that do not include neurologic or neurobehavioral end points.<sup>41</sup> The report noted that further work is needed

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<sup>36</sup> OEHHA. *Response to Peer Review and Public Comments on the August 2020 Public Review Draft "Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes on Children"*. April 2021. p. 106. Available: <https://oehha.ca.gov/media/downloads/risk-assessment/comment/rsppeerrevpubcomms040721.pdf>. Accessed May 8, 2023.

<sup>37</sup> OEHHA. *Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes in Children*. 2021. P. 110.

<sup>38</sup> US Food and Drug Administration (FDA). *Background document for the Food Advisory Committee: Certified color additives in food and possible association with attention deficit hyperactivity disorder in children*. March 30-31, 2011. <https://wayback.archive-it.org/org-1137/20170406211659/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM248549.pdf>.

<sup>39</sup> FDA. *Color Additives Questions and Answers for Consumers*. January 4, 2018. <https://www.fda.gov/food/food-additives-petitions/color-additives-questions-and-answers-consumers>. Accessed April 17, 2023.

<sup>40</sup> Leonardo Trasande, Rachel M. Shaffer, Sheela Sathyanarayana, COUNCIL ON ENVIRONMENTAL HEALTH, Jennifer A. Lowry, Samantha Ahdoot, Carl R. Baum, Aaron S. Bernstein, Aparna Bole, Carla C. Campbell, Philip J. Landrigan, Susan E. Pacheco, Adam J. Spanier, Alan D. Woolf; *Food Additives and Child Health*. Pediatrics August 2018; 142 (2): e20181408. 10.1542/peds.2018-1408. <https://doi.org/10.1542/peds.2018-1408>. Accessed April 23, 2023.

<sup>41</sup> Leonardo Trasande, Rachel M. Shaffer, Sheela Sathyanarayana, COUNCIL ON ENVIRONMENTAL HEALTH, Jennifer A. Lowry, Samantha Ahdoot, Carl R. Baum, FACMT, Aaron S. Bernstein, Aparna Bole, Carla C.

to evaluate the impact of dyes, but stated that eliminating artificial food coloring may provide benefits to children with ADHD.<sup>42</sup>

In addition, since 2010, the European Union has required the warning, “may have an adverse effect on activity and attention in children,” to be placed on foods containing certain synthetic dyes, such as Red 40, Yellow 5, and Yellow 6, and other food dyes not authorized for use in the US.<sup>43</sup>

Therefore, as in *CTIA*, these proposed warnings are not controversial or ideological because they are consistent with statements made by a federal agency to consumers as well as by other public health organizations.

Although industry expressed disagreement with the OEHHA’s conclusion,<sup>44</sup> their disagreement does not make the warnings controversial. In *CTIA*, the government required disclosures that carrying cell phones in certain ways will exceed federal guidelines for radio-frequency radiation exposure.<sup>45</sup> The Court acknowledged that there was “controversy concerning whether radio-frequency radiation from cell phones can be dangerous if the phones are kept too close to a user’s body over a sustained period.”<sup>46</sup> However, despite the plaintiff’s disagreement, the Court concluded that the compelled speech was not controversial because it did not require “retailers to take sides in a heated political controversy” and was a “short-hand description” of what the Federal Communications Commission already required to be disclosed in cell phone manuals.<sup>47</sup> As in *CTIA*, the proposed warnings here do not require manufacturers or retailers to take sides in any heated political discussion, but merely inform consumers that human health risks have been identified by the state of California.

Moreover, the proposed dye warnings are distinct from those in *Cal. Chamber of Commerce*. In that case, the Court found that a cancer warning for acrylamide on foods was controversial because expert and government bodies disagreed on the accuracy of a Proposition 65 warning for acrylamide and OEHHA had not independently confirmed its accuracy. For acrylamide, OEHHA added the chemical to the Proposition 65 warning list “because studies showed it produced cancer in laboratory rats and mice.”<sup>48</sup> When deciding that the warning was controversial, the Court specifically noted that that “[e]ven the State of California has stipulated that it ‘does not know that acrylamide causes cancer in humans.’”<sup>49</sup> and that FDA stated that “warning labels based on the presence of acrylamide in food might be misleading.”<sup>50</sup> The opinion also cited

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Campbell, Philip J. Landrigan, Susan E. Pacheco, Adam J. Spanier, Alan D. Woolf; *Food Additives and Child Health*. Pediatrics August 2018; 142 (2): e20181410. 10.1542/peds.2018-1410  
<https://doi.org/10.1542/peds.2018-1410>. Accessed April 23, 2023.

<sup>42</sup> *Id.*

<sup>43</sup> Annex V of Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20140414&qid=1407766728924&from=EN>. Accessed April 21, 2023. (See link P. 330)

<sup>44</sup> See discussion *Supra* Section II. [Mischaracterizations of the OEHHA Health Effects Assessment](#)

<sup>45</sup> *CTIA*, 928 F.3d at 846-47.

<sup>46</sup> *Id.* at 848.

<sup>47</sup> *Id.*

<sup>48</sup> *Cal. Chamber of Commerce*, 29 F.4th 468 at 473

<sup>49</sup> *Id.* at 479.

<sup>50</sup> *Id.*

several international, state, and federal agencies, as well as professional organizations, that differed in their opinions as to acrylamide's carcinogenicity in humans.<sup>51</sup>

Unlike acrylamide, OEHHA's conclusions on dyes are (1) based on its own systematic assessment of the current body of evidence and is not limited to animals and (2) are aligned with conclusions or statements by FDA, AAP, and the European Union.

First, for synthetic dyes, OEHHA did not merely rely on studies indicating its impact on neurobehavior in animals. The office considered conflicting studies regarding the effects on both humans and animals, systematically weighed the evidence, and conclusively determined that "the scientific literature indicates that synthetic food dyes can impact neurobehavior in some [human] children."<sup>52</sup> The dye warnings therefore differ from acrylamide warnings because the state of California assessed the evidence and explicitly concluded that these dyes are known to adversely impact human children.

Second, unlike in *Cal. Chamber of Commerce* where FDA stated that a warning for acrylamide might be misleading,<sup>53</sup> FDA has not indicated that OEHHA's conclusion on dyes or our proposed warnings are misleading. On the contrary, FDA has indicated that some evidence suggests dyes can impact certain children.<sup>54</sup>

In *Cal. Chamber of Commerce*, the Court also noted that the National Cancer Institute and the American Cancer Society did not find a likely link between acrylamide and cancer.<sup>55</sup> With respect to food dyes there are no major U.S. public health authorities or organizations that deny these dyes' neurobehavioral impacts. In fact, the American Academy of Pediatrics (AAP) has declared synthetic dyes to be compounds of concern and suggested avoiding dyes for some children.<sup>56</sup> Similar dye warnings have also been required in the European Union since 2010.<sup>57</sup>

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<sup>51</sup> *Id.*

<sup>52</sup> OEHHA. *Health Effects Assessment: Potential Neurobehavioral Effects of Synthetic Food Dyes in Children*. 2021. P. 23.

<sup>53</sup> *Cal. Chamber of Commerce*, 29 F.4th 468 at 479.

<sup>54</sup> FDA. *Background document for the Food Advisory Committee: Certified color additives in food and possible association with attention deficit hyperactivity disorder in children*. March 30-31, 2011; FDA. *Color Additives Questions and Answers for Consumers*. January 4, 2018. <https://www.fda.gov/food/food-additives-petitions/color-additives-questions-and-answers-consumers>. Accessed April 17, 2023.

<sup>55</sup> *Cal. Chamber of Commerce*, 29 F.4th at 478.

<sup>56</sup> Leonardo Trasande, Rachel M. Shaffer, Sheela Sathyanarayana, COUNCIL ON ENVIRONMENTAL HEALTH, Jennifer A. Lowry, Samantha Ahdoot, Carl R. Baum, Aaron S. Bernstein, Aparna Bole, Carla C. Campbell, Philip J. Landrigan, Susan E. Pacheco, Adam J. Spanier, Alan D. Woolf; *Food Additives and Child Health*. *Pediatrics* August 2018; 142 (2): e20181408. 10.1542/peds.2018-1408. <https://doi.org/10.1542/peds.2018-1408>. Accessed April 23, 2023; Leonardo Trasande, Rachel M. Shaffer, Sheela Sathyanarayana, COUNCIL ON ENVIRONMENTAL HEALTH, Jennifer A. Lowry, Samantha Ahdoot, Carl R. Baum, FACMT, Aaron S. Bernstein, Aparna Bole, Carla C. Campbell, Philip J. Landrigan, Susan E. Pacheco, Adam J. Spanier, Alan D. Woolf; *Food Additives and Child Health*. *Pediatrics* August 2018; 142 (2): e20181410. 10.1542/peds.2018-1410 <https://doi.org/10.1542/peds.2018-1410>. Accessed April 23, 2023.

<sup>57</sup> Annex V of Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1333-20140414&qid=1407766728924&from=EN>. Accessed April 21, 2023. (See link P. 330)

Therefore, as in *CTIA*, these proposed warnings are not controversial or ideological because they do not force industry to take sides in a heated political discussion (there is no debate that OEHHA has reached the conclusions cited in the warning label), are not in conflict with statements made by a federal agency to consumers, and consistent with findings of other public health organizations.

(2) *The Warnings are Reasonably Related to a Legitimate Government Interest*

The second prong of *Zauderer* test requires the government to have a legitimate interest reasonably related to the disclosure requirement. In *CTIA*, the court held that “[t]here is no question that protecting the health and safety of consumers is a substantial governmental interest.”<sup>58</sup> In that case, the Court found City of Berkeley-required warnings permissible because consumers were largely unaware of the contents of their cell phone user manuals, which disclosed risks.<sup>59</sup>

Here, the proposed dye warnings similarly further public health by informing caregivers and children of the risks to children posed by dyes. Although consumers can identify dyes in ingredients list, many consumers are unaware that dyes present these risks and do not realize they should even be looking for these dyes in their foods.<sup>60</sup> These warnings will help consumers understand and avoid potential adverse neurobehavioral impacts and thereby protect public health.

(3) *The Warnings are Not Unjustified or Unduly Burdensome*

The third prong of the *Zauderer* test requires that the compelled disclosure is not unjustified or unduly burdensome. The problem the government hopes to address must be “real and not purely hypothetical.”<sup>61</sup> But a disclosure does not need to definitively address the problem.<sup>62</sup> A requirement that is not unduly burdensome is one that does not go beyond what is reasonably necessary, and therefore does not risk “chilling” protected speech.<sup>63</sup> A mandated disclosure may be unjustified or unduly burdensome if it “drowns out” an advertiser’s message and “effectively rules out the possibility” of advertising.<sup>64</sup>

As this comment has demonstrated, for dyes, the risk to children is real and not purely hypothetical.

The burden analysis is highly dependent on context. Circuit Courts have upheld mandatory solicitation disclosures applicable to loan lenders that are required to be in the same or larger font as other lender information.<sup>65</sup> A tobacco warning taking up 50 percent of the back and front of

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<sup>58</sup> *CTIA*, 928 F.3d at 845. *Note*, although the Ninth Circuit refers to substantial government interest in *CTIA*, in *Zauderer*, the Supreme Court only required a legitimate government interest.

<sup>59</sup> *Id.* at 845-46.

<sup>60</sup> *See discussion supra* Section [I. Californians Overwhelmingly Want and Need Dye Warnings](#).

<sup>61</sup> *Nat’l Ins. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2378 (2018).

<sup>62</sup> *Zauderer*, 471 U.S. at 651, n. 14.

<sup>63</sup> *NIFLA*, 138 S. Ct. at 2377.

<sup>64</sup> *NIFLA*, 138 S. Ct. at 2378.

<sup>65</sup> *Loan Payment Admin., LLC v. Hubanks*, 821 Fed. Appx. 687 (9th Cir. 2020).



cigarette packages<sup>66</sup> and a single 8.5 x 11” posted notice or 5 x 8” handout to be distributed by cellphone retailers were both found to be constitutional.<sup>67</sup> However, in *Am. Bev. Ass’n v. City &*

*Cty. of S.F.*, the Court of Appeals for the Ninth Circuit, sitting *en banc*, invalidated San Francisco’s sugar-sweetened beverages warning that would have taken up 20 percent of advertising space because a study of similar warnings indicated that the City could accomplish its goal with a warning half of that size.<sup>68</sup>

In our petition, we addressed the potential burden on industry by requesting separate warnings formats for four specific categories of foods and supplements, which are (1) those with packaging of 12 square inches or more available for labeling, (2) those with packaging less than 12 square inches available for labeling, (3) those sold unpackaged or in bulk, and (4) those sold in restaurants.

The two warnings for packaged foods and for bulk and unpackaged items are based on the size and formatting requirements of warnings CDPH already requires for laxatives.<sup>69</sup> There is no evidence that the laxatives warnings, which have been in effect on packaged foods since 1997, have created an undue burden or chilled protected speech. Although the laxative regulations do not prescribe size and formatting requirements for unpackaged goods, there is no reason to believe that the formatting requirements sought in the petition would be more burdensome for unpackaged or bulk goods.

For restaurant foods, the proposed warning makes use of an icon that will be inserted adjacent to the menu item name, with the following warning appearing only once on the menu: “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.” Such warnings similarly are not unduly burdensome, as our proposed warning format was crafted to occupy minimal space while still being readable and understandable to consumers.

This warning would be similar in size to existing federal menu labeling requirements, which require calories to be listed for each menu item and a general statement about nutrition to appear once on the menu.<sup>70</sup> Restaurants should be able to effectively convey the desired information to consumers while bearing the required warnings. Furthermore, a smaller warning is unlikely to be effective in achieving the government’s purpose.

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<sup>66</sup> *Discount Tobacco City and Lottery, Inc. v. U.S.*, 674 F.3d 509 (6th Cir. 2012).

<sup>67</sup> *CTIA*, 928 F.3d at 848-849.

<sup>68</sup> *Am. Bev. Ass’n v. City and Cty of San Francisco*, 871 F.3d 884 (9th Cir. 2017).

<sup>69</sup> Cal. Code Regs. tit. 17, § 10750. Available at

[https://govt.westlaw.com/calregs/Document/IB2C7E1E35A2011EC8227000D3A7C4BC3?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)&bhcp=1](https://govt.westlaw.com/calregs/Document/IB2C7E1E35A2011EC8227000D3A7C4BC3?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)&bhcp=1). Accessed May 12, 2023.

<sup>70</sup> E.g., 21 CFR § 101.11. Available at <https://www.govinfo.gov/app/details/CFR-2015-title21-vol2/CFR-2015-title21-vol2-sec101-11>. Accessed April 28, 2023.



Finally, if our petition is granted, we expect CDPH to engage in further rulemaking, during which the agency will have opportunity to make further adjustments to avoid being unduly burdensome.

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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## Appendix

### *(1) Survey Questionnaire*

#1. Below is an example of an ingredients list of a food product. How often do you read the ingredients list on food labels? **[Select one answer]**

INGREDIENTS: CORN SYRUP, SUGAR, MODIFIED CORNSTARCH, DEXTROSE, WATER, CONTAINS LESS THAN 2% OF GELATIN, TETRASODIUM PYROPHOSPHATE (WHIPPING AID), NATURAL AND ARTIFICIAL FLAVOR, BLUE 1.

1. Never
2. Sometimes
3. Always

#2. True or False: I can tell if a food or beverage contains food dyes by its color. **[Select one answer]**

1. True
2. False
3. I don't know

#4. Which of the following store-bought foods do you think contain food dyes? **[Select as many as apply for 01-04. Randomize 01-04]**



1.



2.



3.



- 4.
5. None of these [EXCLUSIVE]

#5. Which of the following restaurant foods do you think contain food dyes? [Select as many as apply for 01-04. Randomize 01-04]



1. Dairy Queen Strawberry Sundae



2. Arby's Chocolate Shake



3. Fanta Orange at McDonald's



4. Taco Bell's Wild Strawberry Freeze

5. None of these [EXCLUSIVE]

#6. Do food dyes such as Yellow No. 5 or Red No. 40 offer health or nutritional benefits? [Select one answer]

1. Yes
2. No
3. I don't know

#7. Can food dyes cause or worsen any of the following? [Select as many as apply for 01-03. Randomize 01-03]

1. Hyperactivity and/or difficulty paying attention
2. High blood pressure
3. High cholesterol
4. Dyes don't cause or worsen these adverse health effects [EXCLUSIVE]

#8. Do you think foods containing synthetic food dyes in the U.S. should be required to have a warning label on the front of the package? [Select one answer]

1. Yes
2. No
3. I don't know

**#9.** A California government agency has concluded that ‘synthetic food dyes can impact neurobehavior in some children.’ In Europe, warning labels are required on foods containing certain synthetic food dyes that say that the dyes ‘may have an adverse effect on attention and activity in children.’ Knowing this, do you think foods containing synthetic food dyes in the U.S. should also be required to have a similar warning label? **[Select one answer]**

1. Yes
2. No
3. I don't know

*Survey Sample Sociodemographics*

We compared the demographics of the survey sample to California state demographic data as reported by the US Census Bureau and the California Secretary of State, Elections Division (Table A1).

**Table A1.** Self-reported sociodemographic characteristics of survey participants (n = 1,008) compared to California population sociodemographic characteristics.

<b>Characteristic</b>	<b>Proportion of Respondents</b>	<b>CA Population<sup>71,72,73</sup></b>
<b>Gender</b>		
Male	50%	50%
Female	50%	50%
<b>Age (years)</b>		
18-34	31%	-- <sup>74</sup>
35-44	20%	14%
45-54	14%	13%
55-64	15%	12%
65+	20%	15%
<b>State of Residence</b>		
California	100%	100%
<b>Community Type</b>		
Urban	39%	--
Suburban	52%	--
Rural	9%	--

<sup>71</sup> U.S. Census Bureau. American Community Survey 2021. ACS 1-Year Estimates Subject Tables (ACSST1Y2021). Available: <https://data.census.gov/>. Accessed: April 17, 2023.

<sup>72</sup> California Secretary of State, Elections Division. Report of Registration: Odd-Numbered Year Report. 10 February 2023. Available: <https://www.sos.ca.gov/elections/report-registration/ror-odd-year-2023>.

<sup>73</sup> U.S. Census Bureau. Quick Facts: California. <https://www.census.gov/quickfacts/CA>.

<sup>74</sup> CA reports age ranges 15-19 and 20-24. Therefore, we cannot ascertain the proportion of the population aged 18-34 years from the data available; however, people aged 20-34 years make up 14% of the population. Since the survey excluded individuals younger than 18, it is inherent that the survey sample will skew older than the general population of California.

<b>Marital Status</b>		
Married	49%	46.4% <sup>75</sup>
Living with a partner	10%	-- <sup>76</sup>
Single and never been married	28%	38.2%
Separated	2%	1.9%
Divorced	9%	8.9%
Widowed	3%	4.6%
<b>Housing</b>		
Own	54%	55.9% <sup>77</sup>
Rent	38%	44.1%
Live with others at no cost	9%	--
<b>Household size (number of people)</b>		
1	17%	24.0%
2	29%	30.7%
3	18%	16.6%
4+	36%	28.8%
4	20%	--
5+	16%	--
<b>Children &lt;18 years old living at home</b>		
Yes	36%	32.6%
No	64%	67.4%
<b>Total number of children (&lt;18 years old) in the household</b>		
0	64%	--
1	16%	--
2	14%	--
3	4%	--
4+	2%	--
<b>Highest level of formal education completed</b>		
Grade school or less	0%	8.8% <sup>78</sup>
Some high school	2%	6.7%
High school graduate	15%	20.7%
Some college	21%	19.7%
2-year college/technical school	14%	7.9%
4-year college	29%	22.1%
Some postgraduate work	3%	--
Postgraduate degree	16%	14%

<sup>75</sup> U.S. Census Bureau marital status data include all individuals older than 15 years old.

<sup>76</sup> “Living with a partner” was not an option provided by the U.S. Census Bureau, so individuals in this situation are likely included in the group “Single and never been married” in the census data.

<sup>77</sup> U.S. Census Bureau housing tenure groups are “owner-occupied” and “renter-occupied.”

<sup>78</sup> The U.S. Census Bureau’s American Community Survey reports educational attainment for people 25 years and older.

<b>Current employment status</b>		
Work full-time	43%	--
Work part-time	10%	--
Self-employed	9%	--
Student	3%	--
Homemaker	6%	--
Retired	19%	--
Not-employed/unable to work	10%	--
<b>Total household income before taxes<sup>79</sup></b>		
<\$25,000	14%	14.8%
\$25,000-34,999	10%	6.2%
\$25,000-29,999	6%	--
\$30,000-34,999	4%	--
\$35,000-49,999	12%	9.0%
\$35,000-39,999	5%	--
\$40,000-49,999	7%	--
\$50,000-74,999	15%	14.7%
\$50,000-59,999	7%	--
\$60,000-74,999	8%	--
\$75,000-99,999	11%	12.2%
\$100,000-149,999	24%	17.6%
\$100,000-124,999	15%	--
\$125,000-149,999	9%	--
\$150,000-199,999	8%	10.0%
\$200,000+	7%	15.5%
<b>Identify as being of Hispanic/Spanish/Latino descent</b>		
Yes	32%	40.2%
No	68%	59.8%
<b>Racial identity</b>		
White	70%	71.1%
Black or African-American	8%	6.5%
Native American or Alaska Native <sup>80</sup>	3%	1.7%
Asian	11%	15.9%
Other	12%	4.7% <sup>81</sup>

<sup>79</sup> Engine Insights collected 2020 household income before taxes from survey respondents, whereas the U.S. Census Bureau data cited here are from a 2021 survey, meaning the values reported here likely slightly reflect different, but perhaps overlapping, periods of time.

<sup>80</sup> U.S. Census Bureau uses the term “American Indian and Alaska Native.”

<sup>81</sup> This is the sum of “Native Hawaiian and Other Pacific Islander” (0.5%) and “Two or More Races” (4.2%).



<b>Political party identity</b>		
Republican	21%	23.83%
Democrat	49%	46.89%
Independent	21%	22.48% <sup>82</sup>
Something else	4%	6.81% <sup>83</sup>
Not sure	3%	--
Decline to answer	2%	--

The survey was generally representative of the population of California, particularly with respect to gender identity, age, marital status, housing ownership status, presence of children at home, household income, and political party affiliation.

The survey underrepresented people with lower levels of educational attainment, with 0% and 2% of survey respondents reporting their highest level of educational achievement as “grade school or less” or “some high school,” respectively, compared to these individuals comprising 8.8% and 6.7% of the state population, respectively. The survey also underrepresents people who identify as Hispanic/Latino (32% of the survey sample vs. 40.2% of the state), people who identify as Asian (11% in the survey vs. 15.9% of the state). People with a household size of one are also underrepresented in the survey (17% in the survey vs. 24% of the state), while those with a household size of four or more are overrepresented (36% of the survey vs. 28.8% of the state). We cannot speculate as to how this will affect the generalizability of our results to the California population.

Due to differences in which demographics were reported in the survey versus by the US Census Bureau, we cannot determine whether the survey is appropriately representative of the state in relation to community type, number of children in the household, or employment status. There are also differences in how data are reported for several variables. This is most notably the case for age where the youngest group in the survey was 18-34 years old. This grouping intersects with three separate categories used by the US Census Bureau: 15-19 years old, 20-24 years old, and 25-34 years old. Based on the data available, we cannot ascertain the proportion of 18- and 19-year-old people in the state. Therefore, we cannot determine whether the 18-34 year-old group is appropriately represented in the survey.

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<sup>82</sup> Reported by California as “No Party Preference”

<sup>83</sup> Reported by California as “Other”