

March 28, 2023

Honorable Jim Wood, Chair  
Assembly Health Committee  
California State Capitol  
Sacramento, CA 95814

Re: Response to the Food Industry Coalition’s Opposition to AB 418

Dear Chair Wood:

Please find below our response to the industry coalition’s March 13, 2023 letter expressing opposition to AB 418. As you know, know, AB 418 would prohibit an entity from manufacturing, selling, delivering, distributing, holding, or offering for sale food products that contain five health-harming substances — brominated vegetable oil, potassium bromate, propyl paraben, FD&C Red No. 3 (Red 3), and titanium dioxide by January 1, 2025.

In their letter, the food industry rejects the health risks posed by these food additives and maintains that existing regulation is sufficiently protective of consumers. However, as explained below, the U.S. Food and Drug Administration (FDA) has routinely failed to act on new scientific evidence of harm caused by additives that the agency approved decades ago. The FDA is not required to re-review additives and today provides virtually no oversight of new chemicals added to the food supply. The lack of federal action means states must strengthen their laws to ensure that consumers are not harmed by toxic chemicals in food.

**AB 418 would not interfere with ongoing federal regulation of food additives.**

The coalition states that this law “usurps the comprehensive food safety and approval system for these five additives and predetermines ongoing evaluations.” However, it is inaccurate to imply that action at the state level would interfere with or predetermine regulation at the federal level. Passing this measure would be well within California’s constitutional authority to legislate for the state’s public welfare, and will protect Californians with no effect on federal regulation.<sup>1</sup>

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<sup>1</sup> U.S. Const. amend. X.

State action on these food additives is not preempted by federal law. There are no provisions in the federal Food, Drug, and Cosmetic Act (FDCA) that preempt state action to restrict harmful food additives. A recent court decision underscores the power of states to ban food additives even if those additives are allowed by the FDA – in 2021, the Eleventh Circuit upheld a Florida law that banned a certain additive from alcoholic beverages, determining that the state’s restriction was not preempted even though the FDA considered that additive to be “generally recognized as safe” (GRAS).<sup>2</sup>

If AB 418 is passed, the FDA would remain free to act or not act on these food additives as they may continue being legally sold in other states.

**Federal review of food additives is neither “comprehensive” nor “active” and regularly allows hazardous additives to be sold to consumers.**

The industry coalition contends that the federal government has a “comprehensive food safety process” that “provides significant scientific oversight.” In truth, industry’s claims are not borne out by the numbers – 99% of new additives placed on the market since 2000 were never reviewed by the FDA, but rather greenlit by the food industry before being sold to the public.<sup>3</sup> This process is enabled by the “generally recognized as safe” (GRAS) loophole, a provision in the federal Food, Drug, and Cosmetic Act (FDCA) originally meant to allow common ingredients such as vinegar and baking soda to be used in food. However, companies looking to introduce new chemicals to the food supply now routinely exploit the GRAS pathway by appointing industry-favoring panelists to designate chemicals as safe. Companies are not required to even notify the FDA of new chemicals being used in food, let alone seek FDA approval before putting them on the market.<sup>4</sup>

The FDA is also not required to re-review approved additives. Since approving chemicals’ usage decades ago, the agency has not acted on new science that demonstrates these food chemicals’ harms. The FDA has not reviewed titanium dioxide in over a decade, and last reviewed the health effects of Red 3 in 1993.<sup>5</sup> The agency last reviewed the safety of propyl

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<sup>2</sup> [Marrache v. Bacardi U.S.A., Inc.](#), 17 F.4th 1084 (11th Cir. 2021) (“[T]he supervision of the readying of foodstuffs for market has always been deemed a matter of peculiarly local concern.” (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963)) at 1095).

<sup>3</sup> Olivia Backhaus & Melanie Benesh, [EWG analysis: Almost all new food chemicals greenlighted by industry, not the FDA](#), Environmental Working Group (Apr. 13, 2022).

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

<sup>5</sup> Sadiq R. et al., [Genotoxicity of TiO<sub>2</sub>\(2\) anatase nanoparticles in B6C3F1 male mice evaluated using Pig-a and flow cytometric micronucleus assays](#), Mutation Research/Genetic Toxicology and Environmental Mutagenesis (pub. June 2012); Collins TF et al., [Teratogenic potential of FD&C Red No. 3 when given by gavage](#), Toxicological and Industrial Health (pub. July-Aug. 1993).

paraben in 1972 and last reviewed potassium bromate in 1973.<sup>6</sup> All of the additives in AB 418 have more recent science demonstrating their dangers when used in food.

The FDA's underregulation of food additives is a well-established pattern. Regulation of the chemicals targeted in AB 418 is not a priority for the agency and food containing them will continue to be sold to consumers unless state lawmakers take action.

**The FDA regularly fails to respond to petitions and meet other federal statutory requirements to restrict additives that pose public health risks.**

The food industry coalition points to an FDA petition filed by the Center for Science in the Public Interest (CSPI) in 2022 as evidence of the “comprehensive food safety system” working. In actuality, the FD&C Red No. 3 petition is an illustrative example of the FDA's inaction.<sup>7</sup> The FDA first banned Red 3 from cosmetics and externally applied drugs in 1990 after concluding that the colorant causes cancer in rats.<sup>8</sup> The agency told the public at the time that it would “take steps” to eliminate Red 3's use in food, but has still not acted decades later.<sup>9</sup> The Red 3 petition is following up on a decades-old unfulfilled promise, and exemplifies that states cannot rely on the federal system to protect consumers.

The FDA not only has a public health reason to remove Red 3 from the food supply, but also a legal mandate under the Food, Drug, and Cosmetic Act (FDCA). The statute's Delaney clause requires that a color additive “shall be deemed unsafe” and be prohibited from use in food “if it is found ... to induce cancer in man or animal.”<sup>10</sup> A parallel mandate exists in the statute for food additives, which cannot be allowed by the FDA if the chemical is “found to induce cancer when ingested by man or animal.”<sup>11</sup> Government agencies have known that potassium bromate causes cancer since at least 1990, yet the FDA continues to allow the additive in food at levels that could cause harm.<sup>12</sup>

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<sup>6</sup> [Select Committee on GRAS Substances \(SCOGS\) Opinion: Methyl Paraben, Propyl Paraben](#), U.S. Food and Drug Administration (last accessed Mar. 22, 2023) ; [38 Fed. Reg. 20053](#).

<sup>7</sup> [Request To Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs](#), 88 Fed. Reg. 10245 (filed Nov. 15, 2022). Petition available at [https://www.cspinet.org/sites/default/files/2022-10/Red%203%20petition\\_24%20Oct%202022\\_FINAL%20%281%29.pdf](https://www.cspinet.org/sites/default/files/2022-10/Red%203%20petition_24%20Oct%202022_FINAL%20%281%29.pdf).

<sup>8</sup> [21 CFR § 81.10\(u\)](#).

<sup>9</sup> Patricia McLaughlin, [Seeing Red Dye No. 3](#), Chicago Tribune (Apr. 22, 1990) (last visited Mar. 17, 2023).

<sup>10</sup> [21 U.S.C. § 379e\(b\)\(5\)\(B\)](#).

<sup>11</sup> [21 U.S.C. § 348\(c\)\(3\)](#). The Delaney clause banning carcinogenic food additives is relevant for potassium bromate, which has been on the Proposition 65 list for cancer since 1990. [The Proposition 65 List](#), California Office of Environmental Health and Hazard Assessment (last visited Mar. 22, 2023).

<sup>12</sup> [Chemicals Known to the State to Cause Cancer or Reproductive Toxicity](#), California Office of Environmental Health Hazard Assessment (Jan. 27, 2023) (last visited Mar. 17, 2023) (showing that California has known potassium bromate causes cancer since 1990); [Proposition 65 No Significant Risk Levels \(NSRLs\) and Maximum Allowable Dose Levels \(MADLs\)](#), California Office of Environmental Health

The FDA’s delayed action on food additives is a dangerous long-term pattern. It is common for the agency to take years to resolve petitions from public interest groups to amend food additive regulations, despite federal law requiring a response within 180 days.<sup>13</sup> For example, public health groups filed a food additive petition in January 2016, urging the FDA to disallow seven synthetic food additives shown to induce cancer in animals.<sup>14</sup> Despite its statutory obligation to respond within six months, the FDA made a decision to delist the additives almost three years later and after the petitioners sued the agency for unreasonable delay.<sup>15</sup> In another case, a food additive petition urging the FDA to prohibit the use of butylated hydroxyanisole (BHA) has been “under review” since 1990.<sup>16</sup> BHA is a preservative linked to cancer and endocrine disruption that has been on California’s Proposition 65 list for cancer since 1990, yet it is still allowed in food.<sup>17</sup>

The food industry argues that the FDA runs a working regulatory system, but consistently delayed and missing federal action strongly demonstrates the opposite – that the current regulatory system is far from sufficient to protect Californians’ safety.

**Existing California law does not restrict these toxic chemicals in food.**

The industry coalition contends that existing California laws are sufficient because they require “removing chemicals from foods” and “checking alternatives if ... food additives are unsafe or expose consumers to allergies.”

The food industry does not cite or otherwise specify which laws they are referring to in this statement. With respect to laws requiring “removing chemicals from foods,” there are no California laws that restrict these chemicals in food. California’s Sherman Food, Drug, and Cosmetic Law (Sherman Law) authorizes the state Department of Health (CDPH) to promulgate limits on specific food and color additives, but this power has never been used.<sup>18</sup> The industry letter does not provide a source or any evidence to support the claim that companies are already obligated to find alternatives for unsafe food additives or allergens.

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Hazard Assessment (last visited Mar. 17, 2023) (establishing the safe level of potassium bromate as 1 µg/day); [21 CFR § 137.155](#) (FDA regulation allowing potassium bromate in white flour at 50 µg/g).

<sup>13</sup> [21 U.S.C. § 348\(c\)\(2\)](#).

<sup>14</sup> [Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants](#), 83 Fed. Reg. 50490 (available at <https://www.federalregister.gov/documents/2018/10/09/2018-21807/food-additive-regulations-synthetic-flavoring-agents-and-adjuvants>).

<sup>15</sup> *Id.* (Note: All of the seven carcinogenic additives are no longer allowed for use in food. FDA delisted six out of the seven in response to the citizen petition, and delisted one (styrene) as part of a separate rulemaking process that occurred prior to the petition response); [In re Breast Cancer Fund et al. v. U.S. Food and Drug Administration](#), petition for a writ of mandamus (submitted May 2, 2018).

<sup>16</sup> [FAP 0A4216, Petition to prohibit the use of BHA](#), U.S. Food and Drug Administration (filed June 22, 1990, status last updated June 22, 1990) (last visited Mar. 24, 2023).

<sup>17</sup> [The Proposition 65 List](#), California Office of Environmental Health Hazard Assessment (Jan. 27, 2023) (last visited Mar. 24, 2023).

<sup>18</sup> [California Health and Safety Code § 110070](#).

The industry then states that these additives “have been thoroughly reviewed by ... state systems.” The food industry provides no evidence to support their argument that the state has thoroughly reviewed and approved the safety of these chemicals. As mentioned above, CDPH has never utilized its power to restrict toxic food chemicals under the Sherman Law. In fact, existing state reviews *support* the passage of AB 418 – California agencies have identified significant health risks linked to the consumption of potassium bromate, propyl paraben, and Red 3.<sup>19</sup>

The coalition also points to Proposition 65 as establishing safe levels for dangerous chemicals such as potassium bromate, a carcinogenic additive that AB 418 would ban in food. However, Proposition 65 should be understood as evidence supporting the legislation, not an excuse not to pass it. The Proposition 65 No Significant Risk Level (NSRL) for potassium bromate, which has been on the list since 1990, is 1 µg/day.<sup>20,21</sup> FDA regulations currently allow potassium bromate to be added to white flour at rates up to 50 µg/g.<sup>22</sup> This means that a single slice of bread, containing approximately 28 grams of flour, could contain over 1400 times the Proposition 65 safety level and still be in conformance with federal law. Moreover, the NSRL is merely a threshold above which potassium bromate must be disclosed on a warning label on consumer products, not a limit on how much of the additive can be used.<sup>23</sup> As such, existing state regulation points to the need for a stronger approach to toxic chemicals that ensures these additives are not put in food in the first place.

It is clear that existing California law points to a need for stronger consumer protections, not acceptance of the status quo.

### **Ingredient and warning labels are insufficient alone to protect consumers.**

The food industry letter contends that current regulations are sufficient in part because existing state law requires “attaching warning labels” and because federal law “requires ingredient labeling allowing consumers to make informed choices.” The industry coalition

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<sup>19</sup> [Chemicals Known to the State to Cause Cancer or Reproductive Toxicity](#), California Office of Environmental Health Hazard Assessment (Jan. 27, 2023) (last visited Mar. 17, 2023) (Proposition 65 listing of potassium bromate for cancer); [n-Propylparaben](#), CalSAFER (last visited Mar. 24, 2023) (listing of propyl paraben as a “candidate chemical” under the Safer Consumer Products Program run by DTSC); [Report Links Synthetic Food Dyes to Hyperactivity and other Neurobehavioral Effects in Children](#), California Office of Environmental Health Hazard Assessment (Apr. 16, 2021) (finding that artificial colorants including Red 3 are linked to neurobehavioral effects in children).

<sup>20</sup> [Chemicals Known to the State to Cause Cancer or Reproductive Toxicity](#), California Office of Environmental Health Hazard Assessment (Jan. 27, 2023) (last visited Mar. 17, 2023).

<sup>21</sup> [Proposition 65 No Significant Risk Levels \(NSRLs\) and Maximum Allowable Dose Levels \(MADLs\)](#), California Office of Environmental Health Hazard Assessment (last visited Mar. 17, 2023).

<sup>22</sup> [21 CFR 137.155](#).

<sup>23</sup> [California Health and Safety Code §§ 25249.5 - 25249.14](#).

supports its argument by pointing out that health advocates submitted a petition to CDPH to require warning labels on products containing synthetic colorants. The food industry also alludes to California's Proposition 65's label requirements, suggesting that consumers are adequately protected by the Proposition 65 system.<sup>24</sup>

A label warning of a carcinogenic additive is plainly less protective than a prohibition of the additive altogether. Limiting consumer protection to warning labels unreasonably relies upon consumers to not only read and understand the label, but also act upon that information. It is well-established that individual food choices are regularly influenced by a complex set of factors beyond individual control, including access to diverse and healthful foods, employment structures, and histories of food insecurity.<sup>25</sup> Particularly where children are the targeted consumers of candy and other processed foods, a warning label is crucially inadequate to protect them from toxic food chemicals.

Furthermore, as explained above, current efforts by public interest groups to improve food additive safety indicate that the status quo is underprotective, not that it is working. California's own Office of Environmental Health Hazard Assessment (OEHHA) has found that synthetic food dyes are linked to neurobehavioral effects in children, yet artificial colors are still widely used in confectioneries and other processed foods marketed to children.<sup>26</sup> That public health advocates petitioned CDPH to require warning labels is not an example of the current food safety system working, but the opposite – it is an example of *gaps* in the law that require proactive efforts to address.

**AB 418 is an opportunity to ensure food sold in California is as safe as food sold in the European Union.**

Acting on scientific evidence, the EU banned titanium dioxide from food in 2022.<sup>27</sup> Propyl paraben was banned from food in the EU in 2006, and Red 3 has been restricted to only candied and cocktail cherries since at least 1994.<sup>28</sup> Both brominated vegetable oil and potassium bromate are also banned in the EU.<sup>29</sup> With AB 418, California legislators are in a position to act and bring food safety standards on these hazardous additives in line with the EU. In the absence

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<sup>24</sup> *Id.*

<sup>25</sup> [Individual, Household, and Environmental Factors Affecting Food Choices and Access](#), Chapter 4 in Supplemental Nutrition Assistance Program: Examining the Evidence to Define Benefit Adequacy, Committee on Examination of the Adequacy of Food Resources and SNAP Allotments; Food and Nutrition Board; Committee on National Statistics; Institute of Medicine; National Research Council; Caswell JA, Yaktine AL, editors (2013).

<sup>26</sup> [Report Links Synthetic Food Dyes to Hyperactivity and other Neurobehavioral Effects in Children](#), California Office of Environmental Health Hazard Assessment (Apr. 16, 2021).

<sup>27</sup> [Commission Regulation \(EU\) 2022/63](#).

<sup>28</sup> [Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006](#); [European Parliament and Council Directive 94/36/EC](#).

<sup>29</sup> [Regulation \(EC\) No 1333/2008](#).

of federal action, AB 418 would ensure Californians are protected from chemicals that have been scientifically shown to be unsafe. We respectfully reaffirm our support.

Sincerely,

Consumer Reports

Environmental Working Group

Cc: Assemblymember Jesse Gabriel  
Assemblymember Buffy Wicks  
Members, Assembly Health Committee  
Members, Assembly Environmental Safety and Toxic Materials Committee