



January 17, 2024

Environmental Working Group comments to the Food and Drug Administration Docket ID: FDA-2023-N-0937: Revocation of Authorization for Use of Brominated Vegetable Oil in Food

These comments are submitted on behalf of the Environmental Working Group (EWG) in response to the Food and Drug Administration's proposed rule to revoke the authorization for the use of brominated vegetable oil (BVO) in food. The proposed rule would remove section 180.30 of Title 21 of the Code of Federal Regulations, revoking the authorization for the use of BVO as an ingredient in food.

EWG is a national environmental health research and advocacy organization focusing on the potential risks from chemicals in food, water, consumer products and the environment. EWG provides information to consumers about which food chemicals to avoid¹ and maintains a database that rates food products based on concerns about their ingredients, as well as nutrition and processing.² EWG also sponsored the California Food Safety Act, which passed in 2023 and prohibits the sale of food products containing BVO, along with three other food chemicals, in the state of California.³ EWG welcomes the opportunity to provide comments to FDA on the proposed rule.

EWG expresses its strong support for FDA's proposed rule and the agency's efforts to reassess food chemicals and other substances that are approved for use in food but have not been reviewed for decades, despite safety concerns. In light of the state of scientific research on the safety of BVO and health effects related to its consumption, the text and purpose of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its accompanying regulations do not permit the FDA to allow the use of BVO in food. Additionally, EWG supports swift FDA action to prohibit the use of BVO in food so it can be taken out of all food products on the market nationwide as soon as possible.

I. EWG supports FDA's proposed rule because it fulfills the FD&C Act's mandate to prohibit the use of unsafe food additives since BVO does not meet the FDA definition of safe

¹ Iris Myers, *EWG's Dirty Dozen Guide to Food Chemicals: The Top 12 to Avoid*, ENV'TL WORKING GROUP (July 11, 2022), <https://www.ewg.org/consumer-guides/ewgs-dirty-dozen-guide-food-chemicals-top-12-avoid>.

² *User's Guide to EWG's Food Scores*, ENV'TL WORKING GROUP, <https://www.ewg.org/foodscores/content/user-guide/> (last visited Jan. 16, 2024).

³ Press Release, Environmental Working Group, California First State to Enact Ban on Four Harmful Chemicals in Food (Oct. 7, 2023), <https://www.ewg.org/news-insights/news-release/2023/10/california-first-state-enact-ban-four-harmful-chemicals-food>; The California Food Safety Act, A.B. 418, Cal. Leg., 2023–2024 Reg. Sess. (Cal. 2023).

A. There must be reasonable certainty that BVO does not cause harm for FDA to allow its use in food

Section 409 of the FD&C Act states that a food additive shall be “deemed to be unsafe” unless the FDA has issued a regulation prescribing the conditions under which it may be safely used.⁴ The purpose of this section is “to protect consumers against the introduction of . . . untested and potentially unsafe substances . . . into food.”⁵ While FDA has the power to determine whether a food additive is unsafe,⁶ FDA regulations define “safe” and “safety” as “a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use.”⁷ This definition recognizes that it is “impossible” to confirm a particular substance’s safety with absolute certainty.

Among the factors FDA must consider when evaluating the safety of a food additive are 1) “the probable consumption of the substance and of any substance formed in or on food because of its use,” 2) “the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet,” and 3) “safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.”⁸

B. Documented concerns about the safety of BVO in food

FDA is correct in saying it cannot conclude “there is a reasonable certainty of no harm from the use of BVO as a stabilizer for flavoring oils in fruit-flavored beverages.”⁹ The lack of certainty about the harmlessness of BVO can be traced back to FDA’s 1970 withdrawal of its GRAS status and subsequent approval on an interim basis subject to further investigation at the request of the Flavor and Extract Manufacturers Association, an interim status that was never removed.¹⁰

The health effects associated with BVO consumption clearly show a lack of certainty about whether it is harmless when used in food. Animal studies as early as the 1970s have found that consumption of BVO is connected to adverse health effects, including enlargement of the heart, liver, kidneys and spleen; thyroid hyperplasia;

⁴ 21 U.S.C. § 348(a)(2).

⁵ *United States v. 29 Cartons of * * * An Article of Food*, 987 F.2d 33, 35 (1st Cir. 1993).

⁶ *See, e.g., Banfi Products Corp. v. United States*, 40 Fed. Cl. 107, 125 (Fed. Cl. 1997).

⁷ 21 C.F.R. § 170.3(i).

⁸ 21 C.F.R. § 170.3(i); 21 U.S.C. § 348(c)(5); 21 C.F.R. § 170.20.

⁹ *Revocation of Authorization for Use of Brominated Vegetable Oil in Food*, 88 Fed. Reg. 75523, 75526 (proposed Nov. 3, 2023).

¹⁰ *Id.* at 75524.

myocarditis; fatty change in the liver; and arrested testicular development.¹¹ Throughout the 1980s and 1990s, studies continued to reach similar conclusions, even with relatively low doses of BVO consumption.¹²

BVO has also been connected to the bioaccumulation of bromine. The consumption of BVO has long been found to lead to accumulation of brominated fatty acids in the liver, heart and adipose tissue of rats.¹³ One study conducted in 1971 found that bromine levels in human tissue in the United Kingdom, where BVO had been allowed in food until 1970, were significantly higher than in Germany and the Netherlands, where BVO had been banned in food much earlier.¹⁴ BVO is a leading source of bromine bioaccumulation, with a 2012 study finding that the average daily intake of BVO through soft drinks exceeded the intake of other organobromine compounds by over 4,000 times in American adults and over 1,000 times in children.¹⁵

There have been multiple documented cases of bromism – a disease caused by chronic exposure to bromine or its compounds with a wide range of potential symptoms including anorexia, weight loss, nausea, confusion, ataxia, psychosis, delirium, ulcers and bromoderma¹⁶ – tied to daily consumption of BVO-containing beverages. In one case, a patient developed a headache, fatigue, ataxia and memory loss from consuming two to four liters of soda containing BVO every day.¹⁷ In another case, a patient who consumed eight liters of a BVO-containing soda each day developed ulcerated nodules on his hands and fingers.¹⁸

Among the most concerning potential health impacts of BVO consumption are developmental neurotoxicity and reproductive toxicity. A study found that rats fed diets

¹¹ See I.C. Munro et al., *Toxic Effects of Brominated Vegetable Oils in Rats*, 22 TOXICOLOGY & APPLIED PHARMACOLOGY 432 (1972); I.C. Munro et al., *Biochemical and Pathological Changes in Rats Fed Brominated Cottonseed Oil for 80 Days*, 7 FOOD & COSMETIC TOXICOLOGY 25 (1969); Theodore M. Farber et al., *The Toxicity of Brominated Sesame Oil and Brominated Soybean Oil in Miniature Swine*, 5 TOXICOLOGY 319 (1976).

¹² See, e.g., C. Bernal et al., *[Toxicological Effects Induced by the Chronic Intake of Brominated Vegetable Oils]*, 36 ARCHIVOS LATINOAMERICANOS DE NUTRICIÓN 432 (1986); N.O. Mocchiutti et al., *[Chronic Consumption of Brominated Vegetable Oils: Their Effect on Liver Secretion and Catabolism of Plasma Lipoproteins]*, 42 ARCHIVOS LATINOAMERICANOS DE NUTRICIÓN 403 (1992); Y.B. Lombardo et al., *Effect of Brominated Vegetable Oils on Heart Lipid Metabolism*, 20 LIPIDS 425 (1985).

¹³ James F. Lawrence et al., *Brominated Fatty Acid Distribution in the Tissues and Fluids of Rats Fed Brominated Vegetable Oils*, 19 LIPIDS 704 (1984); Farber et al., *supra* note 11.

¹⁴ R.F. Crampton et al., *The Bromine Content of Human Tissue*, 25 BRIT. J. NUTRITION 317, 320 (1971).

¹⁵ Bending et al., *Brominated Vegetable Oil in Soft Drinks – an Underrated Source of Human Organobromine Intake*, 133 FOOD CHEM. 678, 678 (2012).

¹⁶ Christina S. Thornton, *Bromism in the Modern Day: Case Report and Canadian Review of Bromide Intoxication*, 35 J. GEN. INTERNAL MED. 2459 (2020).

¹⁷ B.Z. Horowitz, *Bromism from Excessive Cola Consumption*, 35 J. TOXICOLOGY: CLINICAL TOXICOLOGY 315, 315 (1997).

¹⁸ Debra M. Jih et al., *Bromoderma after Excessive Ingestion of Ruby Red Squirr*, 348 NEW ENG. J. MED. 1932, 1933 (2003).

containing .5 percent BVO displayed severe impacts on behavioral development.¹⁹ Rats fed diets containing 1 percent BVO displayed similar behavioral toxicity, as well as reproductive impacts, including severe difficulty conceiving and reduced maternal body weight and litter sizes.²⁰ Rats fed diets containing 2 percent BVO were unable to reproduce altogether.²¹

C. FDA reassessment of BVO has correctly concluded that BVO is unsafe for use in food

FDA correctly identified four questions about the safety of BVO as a food ingredient, namely its potential for thyroid toxicity, bioaccumulation, developmental neurotoxicity and reproductive toxicity.²² EWG agrees with FDA's decision to focus its initial reassessment studies on thyroid toxicity and bioaccumulation, with the understanding that a finding that consuming BVO caused thyroid toxicity or led to bioaccumulation of bromine would be sufficient for finding BVO is not reasonably certain to be harmless and is therefore an unsafe food additive.²³ This has allowed FDA to act more quickly in banning BVO in foods rather than waiting for the results of additional studies. The fact that FDA has not corroborated previous studies with new research, however, does not minimize the potential risks of BVO consumption regarding developmental neurotoxicity and reproductive toxicity.

FDA and the National Institute of Environmental Health Sciences jointly funded a study conducted by the National Center for Toxicological Research in which rats were exposed to BVO in their diets at different concentrations over the course of 90 days.²⁴ The study found histological changes in the thyroid of male rats at all exposure levels and in female rats at the highest exposure level (.5 percent).²⁵ It also found alterations in hormone-signaling along the hypothalamic-pituitary-thyroid axis in BVO-exposed rats.²⁶ The Center for Food Safety and Applied Nutrition (CFSAN) within the FDA reviewed the study's results, concluding that BVO exposure-related effects on the thyroid were

¹⁹ Charles V. Vorhees et al., *Behavioral and Reproductive Effects of Chronic Developmental Exposure to Brominated Vegetable Oil in Rats*, 28 *TERATOLOGY* 309, 309 (1983).

²⁰ *Id.*

²¹ *Id.*

²² Revocation of Authorization for Use of Brominated Vegetable Oil in Food, 88 Fed. Reg. 75523, 75526 (proposed Nov. 3, 2023).

²³ *Id.*

²⁴ K.A. Woodling et al., *Toxicological Evaluation of Brominated Vegetable Oil in Sprague Dawley Rats*, 165 *FOOD & CHEM. TOXICOLOGY* 113137 (2022).

²⁵ Memorandum from Jeremy Gingrich, Toxicology Rev. Branch – Team 2, Div. Food Ingredients, FDA on Brominated vegetable oil (BVO): Updated safety studies for re-evaluation of interim food additive regulation to Jason Downey, Reg. Rev. Branch – Team 1, Div. Food Ingredients, FDA 2 (Mar. 1, 2023).

²⁶ *Id.*



pathological at all levels and corroborated previous studies connecting BVO consumption to thyroid toxicity.²⁷

The FDA-funded study also assessed bioaccumulation of bromine related to dietary BVO exposure. It found that brominated fatty acids rose in a dose-dependent manner in the heart, liver and adipose tissue of all rats exposed to BVO.²⁸ A second study examined the concentration of bromine at various points following dietary exposure to bromine ranging from 30 to 240 days.²⁹ CFSAN review of this study concluded that brominated fatty acids could persist in animals up to 587 days after BVO-consumption stopped.³⁰ These findings confirmed the results of previous studies on the relationship between BVO consumption and bromine bioaccumulation.³¹

FDA correctly notes that the results of these studies are sufficient to revoke BVO's interim food additive regulation and therefore ban its use in food.³² In fact, because these studies have confirmed – and FDA has itself concluded – that there is not reasonable certainty that the use of BVO in food is harmless, the FD&C Act does not permit FDA to allow the use of BVO as a safe food additive.

D. FDA's proposed rule reaches the same conclusion about BVO's safety as other countries and international safety authorities

Based on the health risks noted above, BVO is not permitted as a food additive in many other countries. This includes the United Kingdom, the European Union, Japan, India, Hong Kong, Australia and New Zealand.³³ The Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives evaluated BVO in 1970 and found that the “evidence suggests that a human epidemiological problem could arise from the use of brominated vegetable oils.”³⁴ It therefore found that

²⁷ *Id.* at 3.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.* at 4.

³³ Revocation of Authorization for Use of Brominated Vegetable Oil in Food, 88 Fed. Reg. 75523, 75524 (proposed Nov. 3, 2023); *Parliamentary Question – E-013572: Banned Emulsifier in Soft Drink*, EUR. PARLIAMENT (July 10, 2015), https://www.europarl.europa.eu/doceo/document/E-8-2015-013572_EN.html; Autumn Swiers, *The FDA Wants to Ban the Use of Brominated Vegetable Oil in Foods*, TASTINGTABLE (Nov. 4, 2023), <https://www.tastingtable.com/1438577/fda-wants-ban-brominated-vegetable-oil-foods/>; Joey Kwok, *Brominated Vegetable Oils in Beverages*, CENTRE FOR FOOD SAFETY: FOOD SAFETY FOCUS (July 2014), https://www.cfs.gov.hk/english/multimedia/multimedia_pub/multimedia_pub_fsf_96_01.html#:~:text=BVO%2C%20which%20may%20be%20identified,stabiliser%20in%20fruit%2Dflavoured%20beverages./

³⁴ JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES, EVALUATION OF FOOD ADDITIVES: SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES AND THEIR TOXICOLOGICAL EVALUATION: SOME EXTRACTION SOLVENTS AND CERTAIN OTHER SUBSTANCES; AND A REVIEW OF THE TECHNOLOGICAL EFFICACY OF SOME ANTIMICROBIAL AGENTS 13 (1970).



an acceptable daily intake could not be set for BVO and concluded it should not be used in food.³⁵

The fact that health experts and policymakers at the international level and in other countries have determined that BVO is not safe to use in food further exemplifies the fact that there are at the very least questions surrounding BVO's safety sufficient to conclude that there is not "reasonable certainty" that it is harmless. The fact that other countries and international agencies agree with the findings of FDA's reassessment studies further bolsters the conclusion that BVO is not safe for use as a food additive.

II. FDA's proposed rule would ensure that consumers are best protected against the health risks of BVO consumption as quickly as possible

A. FDA should revoke BVO authorization for use in food before California's statewide ban becomes effective in 2027

In addition to being banned in other countries, BVO was prohibited for sale or manufacture in California by a state law passed in 2023.³⁶ This prohibition will go into effect on January 1, 2027.³⁷ However, well before the California ban goes into effect, FDA should revoke the authorization of BVO so it is banned throughout the country. FDA's proposed rule would require compliance one year after the rule's effective date, or one year plus 30 days after FDA publishes a final rule.³⁸ Ensuring that BVO-containing products are not on the market as early as almost two years before California's ban takes effect will better protect consumers against bromine bioaccumulation and other BVO-related health problems. Particularly where bioaccumulation is a concern, health risks may persist beyond when BVO is no longer available for consumption. Therefore, it is important to act as quickly as possible to remove BVO-containing products from the market. Additionally, FDA's proposed rule will prevent manufacturers from continuing to sell products containing BVO in states other than California in both the short- and long-term.

B. Products containing BVO are available on the market and disproportionately expose low-income consumers to health risks

Many of the largest beverage manufacturers have discontinued the use of BVO in their products. For example, PepsiCo has phased BVO out of Mountain Dew and Gatorade, and Coca-Cola has removed the ingredient from Powerade and Fanta.³⁹ These

³⁵ *Id.*

³⁶ The California Food Safety Act, A.B. 418, Cal. Leg., 2023–2024 Reg. Sess. (Cal. 2023).

³⁷ *Id.*

³⁸ Revocation of Authorization for Use of Brominated Vegetable Oil in Food, 88 Fed. Reg. 75523, 75526 (proposed Nov. 3, 2023).

³⁹ Ketura Persellin & Melanie Benesh, *Watch for this Harmful Chemical in your Soda*, ENV'TL WORKING GROUP (Jan. 13, 2021), <https://www.ewg.org/news-insights/news/2021/01/watch-harmful-chemical-your->



decisions were largely made in response to public pressure following a 2012 Change.org petition initiated by a teenager that brought attention to the health risks related to BVO and garnered over 200,000 signatures.⁴⁰

There are 75 products containing BVO in EWG's Food Scores Database, which includes over 80,000 food products.⁴¹ Another 44 products are labeled as containing brominated soybean oil, a form of BVO.⁴² The Department of Agriculture's branded foods database lists 601 products containing BVO, although it still includes several PepsiCo products. BVO is most commonly found in store-brand products and lesser-known regional brands.⁴³ For example, BVO is found in Great Value Mountain Lightning – Wal-Mart's version of Mountain Dew – as well as orange sodas from the regional grocery brands Food Lion, Giant and H-E-B, among others.⁴⁴

People with limited incomes are more likely to purchase store brand or regional brand alternatives to name brand products, because they typically cost less.⁴⁵ Therefore, people in communities that experience economic difficulties are disproportionately more likely to consume BVO and suffer from its harmful effects, making the continued use of BVO in food an equity issue.

Furthermore, 96 percent of all shoppers have bought store-brand groceries at some point.⁴⁶ Shoppers are also increasingly choosing store brand over name brand products⁴⁷ – a 2023 survey found that most shoppers plan to buy more store-brand products in the future.⁴⁸

While major brands should be commended for removing harmful ingredients like BVO, this is not a substitute for FDA action. Individual state actions like California's

[soda](#); Danielle Wiener-Bronner, *Coca-Cola Caves to Pressure from Teen to Stop Using Sketchy Ingredient*, ATLANTIC (May 5, 2014), <https://www.theatlantic.com/business/archive/2014/05/coke-to-ban-bvo/361747/>.

⁴⁰ Wiener-Bronner, *supra* note 39.

⁴¹ *Food Scores*, ENV'TL WORKING GROUP, https://www.ewg.org/foodscores/ingredients/7939-BrominatedVegetableOilBVO/search/?ingredient_id=7939-BrominatedVegetableOilBVO&page=1&per_page=48, (last visited Jan. 12, 2024).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ The Harris Poll, *Do Americans Prefer Name-Brands or Store Brands? Well, That Depends*. PR NEWswire (Feb. 11, 2015); *Private Brands: Look Who's Buying Now*, INFORMATION RESOURCES INC. 11–13 (Nov. 29, 2022), <https://www.iriworldwide.com/IRI/media/Library/private-brands-report.pdf>.

⁴⁷ *Consumers Want Store Brand Products — Here's How to Do It Well*, SALSIFY, <https://www.salsify.com/blog/why-consumers-want-store-brand-products#:~:text=Salsify's%20%E2%80%9C2023%20Consumer%20Research%E2%80%9D%20found,go%20ods%20and%20cleaners%2C%20for%20example>, (last visited Jan. 12, 2024).

⁴⁸ *Private Brands: Look Who's Buying Now*, *supra* note 43 at 7.

⁴⁹ Aditi Shrikant, *54% of Shoppers Say They'll Choose Store-Brand Groceries Over Name Brand from Now On—It's Not Just about Cost*, CNBC (Oct. 11, 2023), <https://www.cnbc.com/2023/10/11/54percent-of-shoppers-want-to-buy-more-store-brand-products-in-the-future.html>.

BVO ban are also no substitute for FDA’s proposed rule, particularly since BVO is often found in regional products that may not be sold in California and would have no need to comply with the state law. Because FDA’s proposed rule would completely prohibit the use of BVO in food and beverages, it is an important action that the agency must take to ensure that no Americans are consuming foods and beverages containing unsafe ingredients.

III. Because FDA has concluded that BVO is not safe for use in food, FDA should re-evaluate brominated food additives as a group

One of the factors that FDA must consider when evaluating the safety of a food additive is “the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.”⁴⁹ Therefore, BVO and its impacts on human health must be considered when evaluating related brominated food additives, or those that may cause dietary exposure to bromine. FDA has concluded that BVO is unsafe for use in food based on its potential to cause bromine bioaccumulation and thyroid toxicity, which is associated with bromine exposure.⁵⁰ Because dietary exposure to bromine has been identified as a safety concern, it follows that other food additives that may lead to bromine exposure would represent similar safety concerns.

In particular, potassium bromate, a food additive used as a dough strengthener in breads, has also been linked to thyroid harms, including thyroid cancer.⁵¹ Potassium bromate was also banned in California under the California Food Safety Act⁵² and is found in 209 products according to EWG’s Food Scores Database.⁵³

FDA’s conclusions regarding BVO’s safety would likely extend to other brominated food additives. In light of this, FDA should evaluate brominated food additives as a group and ensure that consumers are not exposed to bromine-related health risks through other channels once BVO is no longer permitted as a safe food additive. FDA should also make clear that its proposed rule would revoke the authorization for all brominated vegetable oils, including brominated soybean oil.

IV. Conclusion

EWG supports FDA’s proposed rule and decision to prohibit the use of BVO as a food additive. The FD&C Act and accompanying regulations require FDA to approve

⁴⁹ 21 C.F.R. § 170.3(i); 21 U.S.C. § 348(c)(5).

⁵⁰ Revocation of Authorization for Use of Brominated Vegetable Oil in Food, 88 Fed. Reg. 75523, 75524 (proposed Nov. 3, 2023).

⁵¹ See, e.g., Magdalena Stasiak et al., *[Relationship Between Toxic Effects of Potassium Bromate and Endocrine Glands]*, 60 ENDOKRYNOL POL. 40 (2009).

⁵² The California Food Safety Act, A.B. 418, Cal. Leg., 2023–2024 Reg. Sess. (Cal. 2023).

⁵³ *Food Scores*, ENV’T WORKING GROUP, <https://www.ewg.org/foodscores/ingredients/8173-PotassiumBromate/search/>, (last visited Jan. 16, 2024).



only additives it deems “safe” for use in food. BVO has been associated with well-documented health harms, and FDA has determined that there is no longer a basis for concluding that BVO is “safe” according to its definition. BVO has been phased out of many major brand beverages and is subject to a California statewide ban. Yet it persists in many store-brand and regional products, underscoring the need for FDA to revoke its authorization. Therefore, FDA’s proposed rule to revoke the authorization for the use of BVO in food fulfills FDA’s mandate to ensure that the nation’s food supply is safe.

EWG commends FDA’s decision to reassess BVO safety in light of evidence and questions about its links to health harms, and encourages FDA to continue to do the same with other food chemicals that have not been reviewed for decades despite links to health risks – starting with other brominated food additives that likely have risks and health endpoints similar to those of BVO.

EWG appreciates the opportunity to provide these comments. Thank you for your consideration.

Sincerely,

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