

Comments on the Proposed Rule: Revocation of Authorization for Use of Brominated Vegetable Oil (BVO) in Food

January 17, 2023

The Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2023-N-0937

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA) Proposed rule to revoke the authorization for use of brominated vegetable oil (BVO) in food.

Founded in 1936, Consumer Reports (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

We commend the FDA for issuing this proposed rule that would ban the use of BVO in food. BVO is a complex mixture of plant-derived triglycerides that have been reacted with bromine, which quickly binds with the triglyceride fatty acid chains. BVO is a flavoring oil stabilizer and emulsifier, whose main use is to help prevent the citrus flavoring oil in beverages from floating to the top, thereby giving them a cloudy appearance.

The evidence is clear that brominated vegetable oil in sodas and other beverages poses an unacceptable risk to our health. The FDA's own studies have conclusively shown that BVO poses toxic risks to the thyroid and other chronic health problems.

As FDA noted, BVO has been used as a flavoring oil stabilizer and emulsifier since the 1920s. In 1958, when the Food Additive Amendment was added to the Food, Drug and Cosmetics Act of 1938, BVO was granted generally recognized as safe (GRAS) status due to its long history of use in food. It should be noted that this 1958 amendment was in response to growing concerns about the safety of food additives. BVO's GRAS status allowed it to be used at levels up to 150 ppm in citrus-flavored beverages.

In January 1970, FDA revoked BVO's GRAS status over concerns of thyroid toxicity, bioaccumulation of bromine in various tissues, developmental neurotoxicity, and reproductive toxicity. In response, the additive industry petitioned FDA to allow continued use of BVO, but at one-tenth the dose previously allowed, e.g., 15 ppm. While not fully convinced about BVO's safety, the FDA permitted BVO to be used on an "interim basis" for three years, while long-term toxicity studies were done. However, in 1974, FDA changed the "interim basis" to "indefinite period."

In 2014, FDA performed a toxicology re-evaluation review of BVO¹. That review concluded that, while there wasn't sufficient evidence for an immediate health threat from BVO under current use conditions (15 ppm), the data were insufficient to derive safe levels for chronic use, aka an acceptable daily intake (ADI). FDA determined that there were still data gaps involving thyroid toxicity, bioaccumulation of bromine, developmental neurotoxicity, and reproductive toxicity.

However, it would be another five years before the FDA decided to act. In conjunction with National Institute of Environmental Health Sciences' Division of Translational Toxicology (then known as the Division of the National Toxicology Program) and the National Center for Toxicological Research (NCTR), it designed and carried out two rodent studies to look at two of the data gaps: thyroid toxicity and bioaccumulation of bromine.

Unlike previous safety studies of BVO toxicity, FDA decided to use low dosages of BVO that were more similar to levels consumed by humans. Using consumption figures from the combined 2015-2018 National Health and Nutrition Examination Survey (NHANES) and assuming that all beverages labeled as containing BVO contain 15 ppm, FDA estimated the mean and 90th percentile dietary exposures of 5 and 9 mg BVO/person/day for an adult (body weight of 60 kg), or 0.08 and 0.15 mg/kg body weight (bw)/day, respectively.

The two studies were finally published in 2022². The thyroid toxicity study involved feeding rats BVO at four dosages in feed—0.002, 0.02, 0.1, and 0.5% BVO for 90 days—while the bioaccumulation study involved feeding rats with two dosages of BVO in feed—0.002% and 0.5% BVO for 90 days. The lowest dose in both studies, 0.002% BVO in feed, translated to an average of 1.3 mg/kg bw/day, is just nine-fold higher than the 90th percentile of dietary exposure for an adult.

Thyroid toxicity, specifically follicular cell hypertrophy, was observed in males at all exposure levels and in females at the highest exposure level. The incidence and severity of this thyroid toxicity in males increased in a dose-dependent manner. More importantly, data on the males showed a disruption in hormone-signaling along the hypothalamic-pituitary-thyroid axis. Thus, BVO appears to be an endocrine disruptor.

The bioaccumulation study found bioaccumulation of lipid-bound bromine in both sexes and at the lowest dose tested (0.002% BVO). Indeed, FDA scientists estimated that brominated fatty acids persisted in the test animals for up to 587 days after BVO was discontinued from the diet.³

The data from these two studies prevented FDA from deriving an ADI. Thus, these two studies are strong enough to provide the data needed to revoke authorization of BVO, even though there are still food safety concerns for developmental and reproductive toxicity from dietary exposure to BVO. FDA concluded that “we no longer conclude that there is a reasonable certainty of no harm from the use of BVO as a stabilizer for flavoring oils in fruit-flavored beverages.”⁴

¹ Gingrich J. 2023. Memorandum: Brominated Vegetable Oil (BVO): updated safety studies for re-evaluation of interim food additive regulation. Dated March 1, 2023.

² Woodland KA, Chitranshi P, Jacob CC et al. 2022. Toxicological evaluation of brominated vegetable oil in Sprague Dawley rats. *Food and Chemical Toxicology* 165:113137. doi:10.1016/j.fct.2022.113137

³ Gingrich 2023. Op cit

⁴ Pg. 4 in *Id.*

We strongly support this proposed rule that would revoke the authorization of the use of BVO in food.

Sincerely,

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