## FDA proposes ban on brominated vegetable oil in food

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The Food and Drug Administration has proposed banning brominated vegetable oil (BVO) in food after new studies found the ingredient used in some citrus beverages could cause adverse health effects.

BVO is used in several sports drinks and sodas and authorized by the FDA for use in "small amounts to keep the citrus flavoring from separating and floating to the top of some beverages," said Jim Jones, FDA deputy commissioner for human foods.

The proposal to be published in tomorrow's Federal Register comes with a 75-day public comment period.

Currently, the ingredient is banned in drinks sold in Europe and Japan. California also recently passed a law prohibiting its use as a food additive.

In a statement explaining the proposed decision, Jones said, "In 1970, the FDA determined BVO was no longer 'Generally Recognized as Safe' (GRAS) and began overseeing its use under our food additive regulations. Over the years many beverage makers reformulated their products to replace BVO with an alternative ingredient, and today, few beverages in the U.S. contain BVO."

PepsiCo and Coca-Cola both pledged to remove the ingredient from their product lines after consumer pushback in 2014.

Consumer Reports cited data from the Environmental Working Group in saying that the ingredient is used in "about 70 sodas and beverages, most of them vibrantly colored and citrus-flavored."

Scott Faber, EWG's senior vice president for government affairs, said that BVO is found in "so-called off-brand products, including store-brand products and lesser-known, smaller brands that are sometimes sold regionally."

Faber said the announcement will "ensure everyone has access to products that don't contain BVO."

"The evidence is clear that brominated vegetable oil in sodas and other beverages poses an unacceptable risk to our health," said Brian Ronholm, CR director of food policy. "Toxic additives like BVO that have been shown to pose toxic risks to the thyroid and other chronic health problems should not be allowed in our food."

In a statement, EWG said, "BVO has been linked to numerous health hazards, including harm to the nervous system. It can also build up in the body, and research has shown a connection between drinking large amounts of BVO-containing sodas over a long period of time and problems such as headaches, irritation of the skin and mucous membranes, fatigue and loss of muscle coordination and memory."

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Jones stated, "Although BVO has a long history of use in foods and was at one time considered GRAS, we have continued to study it to understand any potential health impacts. Recent toxicology studies conducted in collaboration with the [National Institutes of Health] have now given us conclusive scientific evidence to support our proposal to remove the FDA's food additive authorization for BVO."

The proposed rule to revoke BVO's food additive authorization explained that in 2014, FDA reviewed the use of BVO and found deficiencies in the existing studies and conducted new rodent safety studies to evaluate the impact on thyroid toxicity and bioaccumulation.

Wendelyn Jones, executive director of the Institute for Advancement of Food and Nutrition Sciences (IAFNS), stated the updated review was based on science and appreciated the agency's decision to initiate post-market assessments on its own initiative based on scientific evidence, or in response to requests from external stakeholders.

"FDA is a science-first organization who is dedicated to protecting the public health," Jones told *Agri-Pulse* in a statement. "This reassessment of the safety of food ingredients, food contact substances, and contaminants as new, relevant data become available helps protect the U.S. population and reflects why FDA is respected as a world-wide leader."

Ronholm said CR was "encouraged that the FDA has re-examined recent studies documenting the health risks posed by BVO and is taking action to prohibit its use."

Jones left the door open for additional review of ingredients as new information becomes available. He said this decision on BVO is an example of how the "agency monitors emerging evidence and, as needed, conducts scientific research to investigate safety related questions, and takes regulatory action when the science does not support the continued safe use of additives in foods."

Sarah Gallo, Consumer Brands Association vice president of product policy, said the "announcement underscores FDA's continued focus on consumer health and safety and demonstrates its authority in the food ingredient space and its ability to provide timely and informative messages to consumers."

Jones said a decision is "forthcoming" on the agency's current review of color additive regulations, including the use of Red Dye No. 3.

FDA said in its proposed rule that the food industry would need sufficient time to reformulate products and for these products to work their way through distribution.

"Therefore, the compliance date for this rule, if finalized, will be one year after the effective date, to provide the opportunity for companies to reformulate, relabel and deplete the inventory of BVO-containing products prior to enforcing the requirements of the final rule," the agency said.

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