



April 13, 2026

Marty Makary, M.D., M.P.H
FDA Commissioner
Department of Health and Human Services
Food and Drug Administration (FDA)
Docket No. FDA-2026-N-0302

RE: Environmental Working Group Comments on FDA’s request for information on butylated hydroxyanisole (BHA) in human food (Docket No. FDA-2026-N-0302)

The Environmental Working Group (EWG) urges the FDA to take decisive action to remove butylated hydroxyanisole (BHA) from food. BHA has been listed as a known carcinogen under California’s Proposition 65 since 1990.¹ In 1991, the National Toxicology Program (NTP) classified BHA as “reasonably anticipated to be a human carcinogen.”²

Considering these determinations, additional studies that have accumulated over more than 30 years, and the current use data provided in this letter, the FDA has sufficient scientific evidence to act to protect the public from harm associated with adding BHA to food.

EWG is a nonprofit public health and environmental research and advocacy organization, headquartered in Washington, D.C., with staff based in Minneapolis and Sacramento. EWG’s research focuses on understanding health risks from chemical contamination of food, water, consumer products and the environment, and on supporting a healthy indoor and outdoor environment for all communities.

A petition to ban BHA has been pending for over 30 years,³ during which time evidence of risk has accumulated, consumers have voiced increasing concern, and states and retailers have stepped in to fill the regulatory gap.

¹ State of California’s Office of Environmental Health Hazard Assessment. Butylated Hydroxyanisole. 1990. <https://oehha.ca.gov/chemicals/butylated-hydroxyanisole>

² National Toxicology Program. (1991). *Report on carcinogens* (5th ed.). U.S. Department of Health and Human Services, Public Health Service. <https://www.ncbi.nlm.nih.gov/books/NBK590883>

³ U.S. Food and Drug Administration. (1990). *Food additive petition (FAP 0A4216) requesting prohibition of butylated hydroxyanisole (BHA) in food*. https://hfppappexternal.fda.gov/scripts/fdcc/index.cfm?set=FAP-CAP&id=FAP_0A4216



The Delaney Clause, a 1958 amendment to the Federal Food, Drug, and Cosmetic Act, establishes a zero-tolerance mandate. This prohibits the FDA from approving any food additive that has been found to "induce cancer" in humans or animals. Unlike other safety standards that allow for "negligible risk," this provision requires that if a substance is shown to cause tumors in laboratory animals, it must be deemed unsafe for the human food supply.

The NTP classified BHA as "reasonably anticipated to be a human carcinogen," due to its ability to cause tumors in three species of rodents. This classification provides the foundation for a formal FDA finding of carcinogenicity.

Widely cited studies now demonstrate that BHA induces multi-organ DNA damage *in vivo* in tissues shared by humans, including the liver, colon, and bladder (Sasaki et al., 2002).⁴ Furthermore, evidence establishes a human-relevant mode of action by showing that BHA promotes human breast cancer cell growth as a xenoestrogen (Pop et al., 2018)⁵ and leads to testicular dysfunction from endoplasmic reticulum stress and dysregulation of calcium homeostasis (Ham et al., 2020).⁶ Within the 2026 FDA Post-Market Chemical Assessment Program, these findings provide evidence sufficient to trigger the Delaney Clause, requiring the FDA to revoke BHA's approval.

West Virginia has already enacted a law banning BHA from food sold in the state.⁷ Major retailers such as Kroger, Hy-Vee and Aldi prohibit BHA in their store brands.

EWG maintains a searchable food products database, Food Scores,⁸ containing thousands of products with product label information provided by LabelINSIGHT®⁹. In a subset of this data consisting of new product labels recorded between 2023 and 2025, there are 172,000 food products. Of these products, 1,726 contain BHA. The top grocery aisles include frozen foods;

⁴ Sasaki, Y. F., Kawaguchi, S., Kamaya, A., Ohshita, M., Kabasawa, K., Iwama, K., Taniguchi, K., & Tsuda, S. (2002). The comet assay with 8 mouse organs: results with 39 currently used food additives. *Mutation Research/Genetic Toxicology and Environmental Mutagenesis*, 519(1-2), 103–119.

[https://doi.org/10.1016/S1383-5718\(02\)00128-6](https://doi.org/10.1016/S1383-5718(02)00128-6)

⁵ Lee, S., Park, Y., & Choi, K. C. (2018). Butylated hydroxyanisole and butylated hydroxytoluene promote human breast cancer cell growth through the activation of estrogen receptors. *Environmental Toxicology*, 33(11), 1144–1153. <https://doi.org/10.1002/tox.22620>

Pop, A., Drugan, T., Gutleb, A.C., Lupu, D., Cherfan, J., Loghin, F., Kiss, B. (2018) Estrogenic and anti-estrogenic activity of butylparaben, butylated hydroxyanisole, butylated hydroxytoluene and propyl gallate and their binary mixtures on two estrogen responsive cell lines (T47D-Kbluc, MCF-7). *J Appl Toxicol.* 38(7):944-957. <https://doi.org/10.1002/jat.3601>

⁶ Ham, J., Lim, W., Whang, K. Y., & Song, G. (2020). Butylated hydroxyanisole induces testicular dysfunction in mouse testis cells by dysregulating calcium homeostasis and stimulating endoplasmic reticulum stress. *Science of The Total Environment*, 702, 134791. <https://10.1016/j.scitotenv.2019.134775>

⁷ West Virginia Legislature. (2025). *House Bill 2354: Relating to prohibiting certain unsafe food additives* (W. Va. Code §§ 16-7-2, 16-7-4, 18-5D-3A).

https://www.wvlegislature.gov/bill_status/bills_text.cfm?billdoc=hb2354+sub+enr.htm&i=2354&sesstype=RS&yr=2025

⁸ EWG's Food Scores. 2026. <https://www.ewg.org/foodscores/>

⁹ NIQ Label Insight. <https://nielseniq.com/global/en/landing-page/label-insight/>

snacks, cookies and candy; deli; meat and seafood; and bakery items (Figure 1). Further broken down into product categories, the data show the top foods containing BHA include frozen pizza; sausages, hot dogs and brats; and cookies and biscuits (Figure 2).

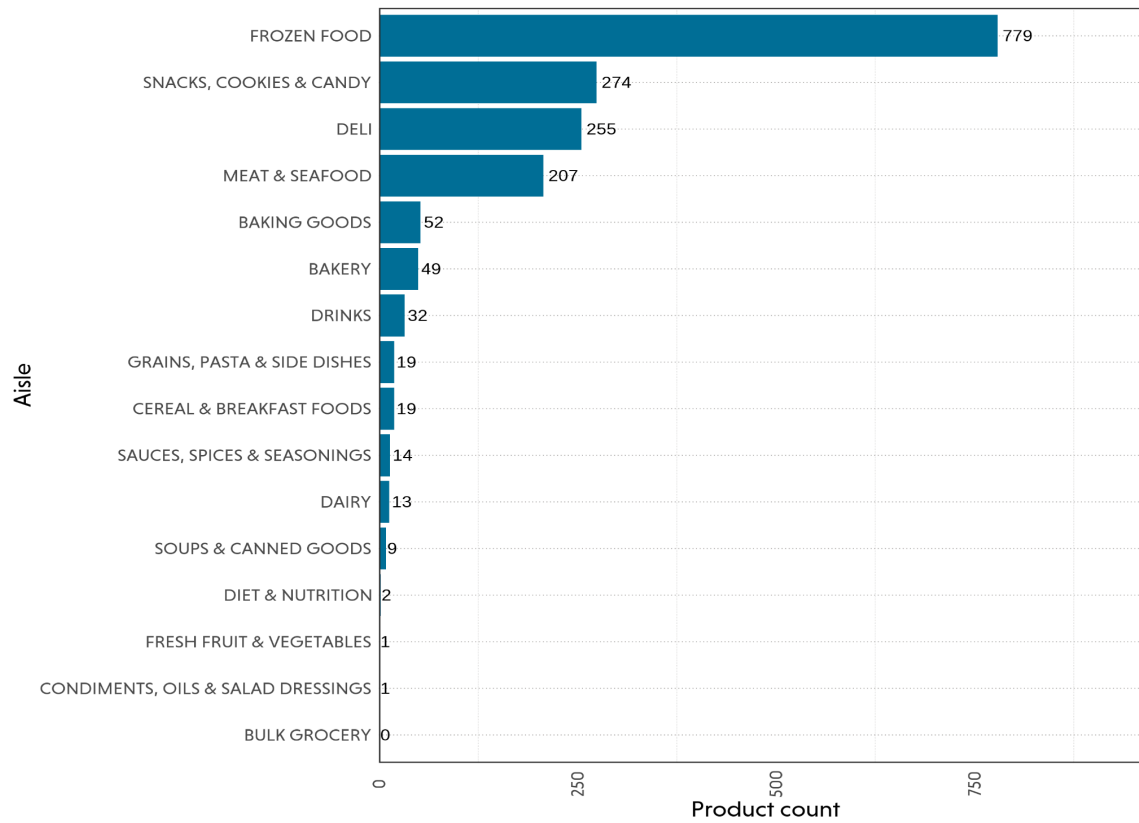


Figure 1. Number of products containing BHA in Food Scores grocery aisles.

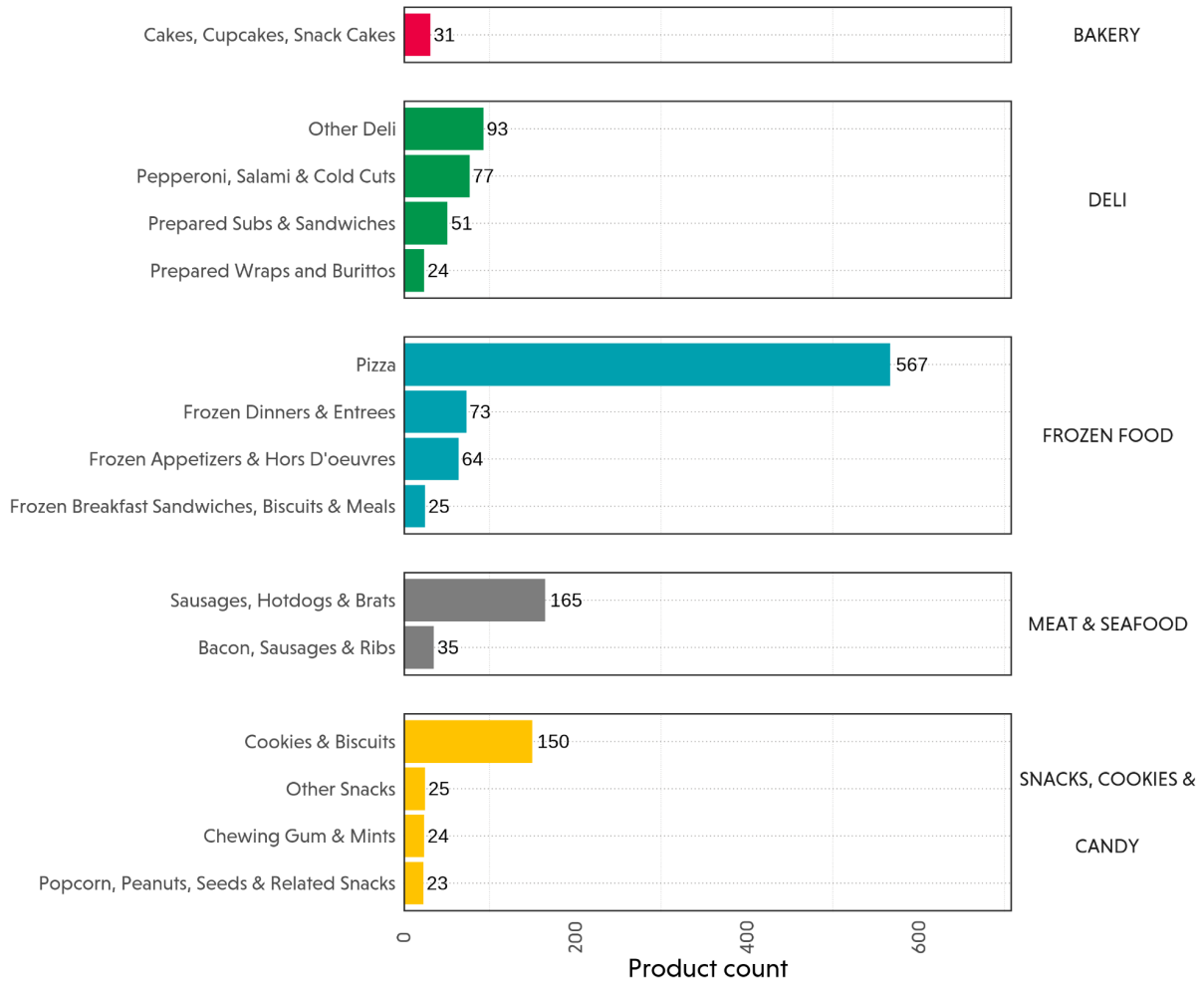


Figure 2. Number of products containing BHA in Food Scores by product categories from the top five grocery aisles.

Dietary exposure to BHA is likely non-uniform across populations, as it is primarily present in processed foods such as frozen meals, cured meats, and packaged baked goods. These food categories are commonly consumed by children, raising the relevance of exposure in younger age groups as well as in those that consume higher amounts of processed foods.



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EWG appreciates the opportunity to provide these comments and strongly urges the FDA to move swiftly to remove BHA from foods.

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